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HEALTH TECHNOLOGY CASE STUDY 32

The Hemodialysis Equipment and Disposables Industry

DECEMBER 1984

This case study was performed as part of OTA's Assessment of

Federal Policies and the Medical Devices Industry

Prepared for OTA by:

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Preface

The Hemodialysis Equipment and Disposables Industry is Case Study 32 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Federal Policies and the Medical Devices Industry*, which was requested by the Senate Committee on Labor and Human Resources and endorsed by the Senate Committee on Veterans' Affairs. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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[d]Background Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[e]Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[f]Background Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

[g]Background Paper #2 to *Technology and Handicapped People*.

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OTA Note

These case studies are authored works commissioned by OTA. Each author is responsible for the conclusions of specific case studies. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of review and revision, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view.

1.
Introduction and Summary

1. Introduction and Summary

INTRODUCTION

End-stage renal disease (ESRD) afflicts approximately 96,000 people in the United States (25, 102). In the course of treatment for this disease, most patients and their providers use an array of products produced by the hemodialysis equipment and supplies industry. This case study offers an analysis of this relatively new U.S. industry. Its existence is a consequence of modern medical advances that have made hemodialysis a viable treatment for ESRD. Moreover, it would be difficult to think of another industry that has been so clearly and directly shaped by Federal policy.

Federal policy continues to be critical to the industry's development. Recent Federal initiatives have changed the rules under which treatment for ESRD is reimbursed. Federal policymakers are also being asked to evaluate certain current practices in treatment. The decisions made will influence, to a significant degree, the structure and economic performance of the industry. In light of this, the case study is particularly timely.

SUMMARY

Treatment Approaches

The two major treatment options for ESRD are transplantation and dialysis. At present transplantation is a solution for a small minority of patients, but with major advances of the recent past in transplantation techniques and immunosuppressive drugs,[1] its use may grow in the future. Nevertheless, at present the vast majority of patients undergo regular dialysis treatment, during which the patient's blood is cleansed of accumulated waste products.

In 1983, 86 percent of dialysis patients (61,722 people) chose a form of dialysis known as hemodialysis (102). In this modality the patient's blood is pumped from the body by a machine, subjected to dialysis, and then returned to the body in a continuous extracorporeal blood loop. Dialysis occurs as the blood passes through a dialyzer, or artificial kidney. Patients must undergo this treatment about three times per week in sessions running about 3½ to 5 hours each. This can be accomplished in a hospital-based center, in a freestanding facility, or at home.

A major alternative form of dialysis, chosen by 12 percent (8,688 people) of ESRD patients in 1983, is continuous ambulatory peritoneal dialysis (CAPD) (102). In CAPD, dialysis occurs within the patient's body across the peritoneal membrane. CAPD requires a manual exchange of fluid every 4 to 6 hours, but it can be done at home and it frees the patient from dependency on a dialysis machine. Although patients experience some risk of developing peritonitis, the modality has been growing in popularity.

The Market

The market for dialysis equipment and disposables has undergone rapid growth since 1972 when Congress passed legislation extending Medicare coverage to patients with ESRD, regardless of age. Since its inception the number of beneficiaries of this program has grown by more than 700 percent (from about 11,000 to 89,000 people[2]). As

[1]For further information, see U.S. Congress, Office of Technology Assessment, *The Use of of Immunosuppressive Drugs in Kidney Transplantation*, Staff Memorandum, Washington, DC, March 1984.

[2]Approximately 7 percent of the 96,000 ESRD patients are not Medicare beneficiaries.

of 1983, program costs were estimated at more than $1.7 billion annually (102).

The firms that produce dialysis equipment and disposables now have total sales of roughly $500 million. They sell their products to hospitals, to free-standing facilities (proprietary and nonproprietary), and to patients themselves. According to traditional economic measures, the industry is highly concentrated (i.e., only a few sellers have a large market share). At the same time the number of separate buyers is large. However, although profits in the industry were apparently quite attractive several years ago, they have been increasingly squeezed. Data presented in this case study indicate that prices have fallen; for example, over the past 5 years, the prices of dialyzers, which have constituted about 40 percent of the industry's sales, have fallen, *after* adjusting for inflation, by 34 percent.

The difficulties firms have experienced in the dialyzer market in recent years are the result of a combination of factors. It seems clear that there has been overcapacity in the industry. Firms expanded production during the good times only to find that overall demand for new dialyzers leveled off and now is actually decreasing. The decrease has resulted in part from buyers' attempts to reduce costs, and those efforts, in turn, have been stimulated by Federal efforts to control the costs of the ESRD program.

Future prospects for the industry as a whole are uncertain. The cost-control pressures are likely to persist. The dialyzer market, in particular, is likely to continue to decline as dialyzer reuse continues and patients move to modalities, such as CAPD (continuous ambulatory peritoneal dialysis), that do not use dialyzers. Firms supplying dialyzers are likely to respond, in part, with diversification within and outside the dialyzer area. In addition, they will probably attempt to develop equipment that can effectively reduce the costs of treatment.

Major Policy Issues

Future prospects for the industry will largely depend on the resolution of some major policy issues. Three areas of policy in particular were considered in the case study. They are: the reimbursement procedures for dialysis care, the Federal contribution to research on ESRD, and the practice of "reuse" of dialyzers. The case study draws some conclusions in each area.

Reimbursement

Perhaps the most notable and most controversial of these issues is the new Federal reimbursement rules for the ESRD program that were established in 1983. These rules are aimed at controlling program costs, in particular by encouraging home dialysis. The rules are likely to have a myriad of direct and indirect effects on the nature of care and thus on the hemodialysis equipment and disposables industry.

The rules have been hailed as the initiation of prospectively set rates. Although the new rules do involve prospective reimbursement—pre-set payment "screens" or maximums known in advance to facilities and patients—so did the previous payment procedure, albeit perhaps to a lesser extent. Under the previous rules, if costs differed from the screen, the facility incurred a loss or surplus accordingly, but hospitals (although not independent facilities) were almost routinely granted exceptions to the screen. Nevertheless, there is some evidence that overall the screen did stimulate cost-control efforts.

It is likely that the new rules will have some of the desired effect. Since exceptions will apparently be granted much less readily, facilities now have a stronger financial incentive to control costs. Moreover, because home dialysis is less costly to the facility, but is reimbursed at the same rate as dialysis performed in the facility, there is a clear incentive to have patients treated at home. Whether the present rates are the most appropriate way to achieve this goal is debatable. The rates themselves seem to have been developed through a less than rigorous statistical procedure, and they offer no clear direct incentive to patients and only limited incentives to physicians for home dialysis. Thus, they could conceivably create conflicts between the facilities that wish to lower costs (and generate surpluses) and physicians and patients. Such conflicts are not apt to enhance the quality of care or, indeed, to contribute to efficient care.

Patients have no direct financial incentive to go home, because the patient's required payment is independent of the setting. Although the Health Care Financing Administration (HCFA) has noted that facilities may want to share some of their profits from home dialysis cases with the patients themselves, it is unclear to what extent facilities will take up this idea (93).

If the objective is to encourage home dialysis, stronger incentives should be directed at patients, who, after all, must make the ultimate choice of setting. If patients were offered a financial incentive to dialyze at home—by being allowed to share in the cost savings attributed to home dialysis—they might be more inclined to choose this setting. Such an incentive, which allows patients themselves to balance benefits and costs, does not appear to have been seriously considered (20). Congressional legislation in 1978 did try to eliminate one financial disincentive to home dialysis by allowing for payment to home dialysis aides. This payment was attractive because home dialysis generally requires the assistance of a trained aide. Although a spouse or other close friend or family member can provide such assistance, a notable time burden is imposed. Payment to an aide is meant to reflect the time costs incurred. However, this congressional provision apparently was not effectively implemented. On balance under the new rules, home dialysis may contribute to the facilities' financial interests but not directly to the patients'.

The impact of these rules on the equipment and disposables industry depends on how effective the rule changes are in achieving their stated objectives. If facilities feel the pressure to reduce costs, they will in turn put pressure on their suppliers. Suppliers will thus have an incentive to compete more than previously on the basis of price and less on the basis of other attributes of the product. At the same time, suppliers may be stimulated to develop cost-reducing innovations. If the effect of the rules is to shift patients to newer modalities such as CAPD, the industry will also respond. Industry resources will be shifted toward those products offering the greatest profit potential, which depends ultimately on the patient base associated with the product.

On balance, the industry will certainly survive the new rules, although its form and structure may undergo some change. Profitability will depend on how facilities and patients respond to the rules and on how creatively the industry can react.

Federal Research

The second major policy issue concerns research. The Federal Government has supported considerable research on ESRD and has contributed to development of many of the products sold by the equipment and disposables industry. However, this Government research contribution has declined, particularly in the area of maintenance dialysis, the area most likely to affect the industry. The long-term consequences are likely to be a decline in innovation in the industry.

Federal-Government-supported research provides a base from which industry can build. As the research base diminishes, private industry has less on which to build. The profitability of its research and development (R&D) activities may diminish, and as a result less R&D will be done. In the long run, the quality and cost efficiency of care depend on such R&D. Private incentives may not generate the socially optimal amount of R&D.

In assessing research, one must recognize that there are competing uses of scarce funds. This case study has no basis on which to conclude that the ESRD program is more worthy of funds than other programs. It is therefore appropriate that some administrative decisions be made on the basis of available expert opinion and perceived social goals. However, the activities of the various agencies responsible for research should be coordinated to assure that whatever objectives are agreed upon are pursued efficiently and effectively.

Dialyzer Reuse

The third major issue facing the industry involves dialyzer reuse. Increasingly, dialyzers, which are labeled by manufacturers for single use only, are being reprocessed and used again, often multiple times. This reprocessing involves a rinsing of the used dialyzer, followed by cleaning and disinfection or resterilization. Critics of the practice express concern about the possible adverse

consequences for patients. These may result from the diminished performance features of a reused dialyzer as well as from the introduction of chemicals used in reprocessing. However, at present, medical opinion views reuse as an acceptable practice, as long as the reprocessing is done with appropriate care. From an economic perspective, reuse appears attractive. Cost savings are undoubtedly present—but only if there are no substantial, negative, medical consequences to the practice. If reuse is associated with increased morbidity or mortality, such costs would have to be included in any cost analysis. Although projected direct cost savings are large, they could be outweighed by the indirect costs of adverse medical consequences.

Again, the current economic argument seems to support reuse. It seems to follow as well that Federal policy be directed toward seeing that reuse be done appropriately. The Government through the Food and Drug Administration could encourage the adoption of guidelines for reprocessing, for the costs of inadequate reprocessing could be severe. Since increases in reuse are likely, poor reprocessing procedures may result. In essence, care should be taken that reuse, one result of cost-control measures, does not, on balance, increase the full social costs of the ESRD program.

Note that these arguments are not contingent on the possible negative effects increased reuse may have on particular manufacturers. Clearly, reuse will pressure firms, particularly weaker firms, to lower prices, thus decreasing profits. In the short run, the lower price seems attractive, particularly to providers. On the other hand, these price reductions could result in firms' exiting from the market, which might ultimately result in a less competitive industry and higher monopoly-like prices. However, such pricing would require at least tacit coordination among remaining manufacturers and might be hampered by the international nature of competition and the possibility for cost competition among treatment modalities. Overall, such concerns seem remote.

The manufacturers of hemodialysis equipment and disposables belong to an unusually dynamic industry, which experienced rapid growth and attractive profits during one phase of its relatively short existence and decreased profits and sales, notably at least in dialyzers, in its current phase. Clearly more changes are in store.

Federal policy has played a critical role throughout. The market grew with the onset of Medicare coverage and has responded to ongoing Federal efforts at controlling the costs of the coverage. It is a market that in many respects is the creation of Federal policy. Its future shape remains intimately tied to that policy.

The remainder of this case study presents evidence pertaining to the conclusions above. Chapters 2 and 3 describe the available treatment approaches to ESRD and their equipment requirements. Chapters 4 and 5 analyze the industry. Finally, policy issues emanating from the industry are raised and discussed in chapter 6.

2.
Treatment Approaches

2. Treatment Approaches

Hemodialysis is one of the three major treatment approaches for end-stage renal disease (ESRD). The others are peritoneal dialysis and transplantation. Each treatment involves a somewhat different array of equipment and supplies. This section briefly describes each approach and discusses the associated equipment. Table 1 shows the number of ESRD patients enrolled in the Medicare program who utilized each treatment modality during 1983.

Table 1.—Estimated Number of End-Stage Renal Disease (ESRD) Patients in the United States by Type of Treatment, 1983

Estimated number of ESRD patients in the United States	95,687[a]
Estimated number of Medicare and nonMedicare ESRD patients receiving treatment as of Dec. 31, 1983: Hemodialysis	61,722
Intermittent peritoneal dialysis	1,572
Continuous ambulatory peritoneal dialysis	8,688
Kidney transplants	6,112
	78,094[a]

[a]The difference between the estimated number of ESRD patients in the United States (95,687) and the estimated number of patients receiving treatments (78,094) may be attributable to the fact that patients who received transplants from 1980 to 1982 were still considered to be ESRD beneficiaries in the Medicare program in 1983.

SOURCES: P. W. Eggers, Office of Research, Health Care Financing Administration, Baltimore, MD, personal communication, February 1984; and U.S. Department of Health and Human Services, Health Care Financing Administration, ESRD Data Branch, "End-Stage Renal Disease Program Quarterly Statistical Summary," Baltimore, MD, June 15, 1984.

DESCRIPTION OF ALTERNATIVES

A healthy kidney performs a variety of functions within the body. It filters the blood, removing the waste products built up from dietary intake and physical activity; it regulates fluid and chemical balance in the body; and it facilitates hormone secretion, assisting in the regulation of blood pressure and the prevention of anemia. In a patient suffering from ESRD, the kidney has ceased to adequately perform these life-sustaining functions.

Treatments for ESRD seek to compensate in various ways for the renal failure (52). Conceptually, the most direct correction is transplantation. A health kidney from a donor, living or recently deceased, is transplanted into the patient. If the transplant is successful, the new kidney will take on the normal kidney functions and the patient, barring other complications, can lead a nearly normal life.

Unfortunately, although transplantation appears an attractive solution in principle, its practical implementation is often quite difficult. Finding an appropriately matched donor kidney is not easy since the body has a strong innate tendency to reject the foreign organ. In addition, immunosuppressive therapy, which has many deleterious side effects, is necessary to prevent kidney rejection. Although graft retention rates have apparently been improving, success is hardly assured (48,49,89). During graft rejection, patients are likely to suffer other complications and must either return to dialysis or undergo another transplantation.

At present, because of these difficulties, renal transplantation remains a treatment for less than 7 percent of U.S. ESRD patients annually (6,112 patients in 1983) (102). The future is unclear. Some observers feel transplantation may work for only a small percentage of the patient population; others believe that the new immunosuppressive drugs, such as cyclosporine, hold promise for more successful transplants in the future. The lat-

ter group see an inadequate supply of donor organs as the major stumbling block to transplantation (81).

Dialysis, the major alternative to transplantation, offers an artificial mechanism for performing kidney functions. In hemodialysis, blood is pumped from the patient's body, subjected to a process of dialysis, and then returned to the body in a continuous extracorporeal blood loop. Dialysis occurs as the blood is passed through a hemodialyzer, or artificial kidney. In the hemodialyzer (or, simply, dialyzer) the blood flows next to but separate from another fluid, a dialysate. The blood and the dialysate are separated from each other by a semipermeable membrane. The patient's blood, because of the renal failure, contains accumulated waste products and abnormal levels of electrolytes. The dialysate, on the other hand, is free of waste products and contains desirable concentrations of physiological chemicals. Via diffusion and osmosis, waste products and other molecules pass through the semipermeable membrane so the blood can again take on its appropriate properties. Furthermore, by regulating pressure on either side of the membrane, buildup of excess body fluids can be effectively removed through the blood to the dialysate.

Patients on hemodialysis typically are dialyzed three times per week, for sessions ranging from about 3½ to 5 hours each. These patients can be dialyzed at home or in hospital-based or freestanding dialysis facilities or centers. Hemodialysis was the treatment chosen by about 89 percent of the patients with ESRD in 1982 (25).

Another form of dialysis, peritoneal dialysis, has been increasing in popularity in recent years. The two forms of dialysis differ in the nature of the semipermeable membrane separating the blood and the dialysate. This difference leads to different methods of dialysis therapy. In peritoneal dialysis, the peritoneum, the membrane surrounding the abdominal organs and lining the abdominal cavity, is utilized in vivo; thus, dialysis occurs within the patient's body rather than via an extracorporeal blood loop. A permanent catheter is inserted into the abdomen, and the dialysate fluid is introduced through the catheter into the peritoneal cavity. The fluid is allowed to remain for varying periods of time, during which dialysis occurs across the semipermeable peritoneal membrane. Later the dialysate fluid is drained out through the catheter and discarded.

The various kinds of peritoneal dialysis reflect variations in the timing of this process. In intermittent peritoneal dialysis (IPD) an automatic machine performs intermittent treatment three to four times per week. Typically, the patient is dialyzed for about 12 hours per treatment, during which the dialysate is automatically exchanged from the peritoneal cavity every hour. Continuous cycling peritoneal dialysis (CCPD) is a variation of IPD involving the use of a machine to warm and cycle the dialysate in and out of the peritoneal cavity automatically about every 4 hours overnight as the patient sleeps. Normally, some fluid is left in the abdomen during the day. Continuous ambulatory peritoneal dialysis (CAPD) involves a continuous, manual exchange of dialysate, roughly every 4 to 6 hours. CAPD offers the advantage of freeing the patient from dependency on a machine. It was chosen by about 10 percent of the ESRD population in 1982 and is, thus, the most popular form of peritoneal dialysis (25).

The relative clinical effectiveness of the modalities remains a subject of study. For various medical or psychological reasons some patients may do better on certain modalities, but there are no controlled, long-term, clinical trials on which to make an overall judgment. Hemodialysis in a dialysis center remains the general historical standard for care. In this regard, a recent analysis done for the Office of Technology Assessment (OTA) concludes that "CAPD appears to be an acceptable alternative to hemodialysis for, at least, selected persons with end-stage renal disease" (86). The authors note that short-term survival rates for the two modalities appear similar, but CAPD patients may be slightly more likely to be hospitalized than either home or in-center hemodialysis patients. This hospitalization is usually because of peritonitis, which many patients on CAPD develop (76).

PATTERNS OF CHOICE AMONG MODALITIES

Choice of modality and treatment setting (home or in-center) depends on a variety of factors reflecting not only the patient's medical condition but also the patient's and physician's personal preferences. The decision to undergo dialysis at home is complicated by concerns about the availability of an assistant to help in dialysis and the cost and disruption the machinery can cause. Also, a patient being dialyzed at home must psychologically balance the responsibilities and the rewards associated with self-care.

The set of choices to be made has varied somewhat over time. With regard to setting, table 2 notes that in 1982 home dialysis was the choice of about 18 percent of dialysis patients. Prior to the enactment of the Federal Government's ESRD program in 1972, the percentage at home was as high as 40 percent; it declined sharply after the program was established but seems to be gradually creeping up. Of course, these percentage changes are based on a patient population whose size and characteristics have also changed.

The percentage of dialysis patients at home varies considerably among States. Some have more than half of their patients at home (e.g., Washington) while others have less than 10 percent (e.g., Illinois). The nature of the facility with which patients deal influences the choice. Hospitals send a greater proportion of patients home than do free-standing facilities (20).

Table 2.—Percent of Dialysis Patients Treated at Home by Year

Year	Percent at home
1972	40
1973	33
1975	16
1976	14
1977	12
1978	12
1979	13
1980	14
1981	16
1982	18

SOURCES: Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981); C. Davis, Administrator, Health Care Financing Administration, testimony at hearing, *Proposed Prospective Reimbursement Rates for the End-Stage Renal Disease Program*, before the Subcommittee on Health of the Committee on Finance, U.S. Senate, Mar. 15, 1982 (Washington, DC: U.S. Government Printing Office, 1982); Kidder, Peabody & Co., *Baxter Travenol Laboratories, Inc.: CAPD Update*, Company Follow-up, New York, Aug. 16, 1982; and P. W. Eggers, Office of Research, Health Care Financing Administration, Baltimore, MD, personal communication, February 1984.

The percent of patients being dialyzed at home also varies among countries. The U.S. rate is very similar to the overall European rate of roughly 17 percent (50). However, there are variations among countries. Great Britain, for example, sends more than half of its patients home, whereas other countries (e.g., The Netherlands and Spain) tend to send less than 10 percent home (1). Such differences may reflect differences among nations in the institutional setting for medical care.

Among approaches, CAPD's share of U.S. patients represents a growth in popularity over the past few years (86), which many market analysts predict will continue (46,79). Similar growth has been evidenced in other countries, although as of the end of 1981, only 6 percent of the European dialysis patients were being treated with this approach (50). As with home dialysis in general, there is considerable intercountry variation. In Canada, about 30 percent of the patients are on CAPD, but in Spain and West Germany, the figure is below 5 percent (46,50).

CAPD is a home-based modality, and thus its use is linked closely with the decision to dialyze at home. Most new patients choosing home dialysis are choosing CAPD, and roughly 68 percent of home patients were on CAPD in 1983 (14,66). At the same time, however, "procedure survival" on CAPD, i.e., the percent of patients remaining on the treatment for a given period, is somewhat low. Recent U.S. figures show rates of 62 percent after 1 year and 56 percent after 18 months (66). The experience in Europe shows even lower procedure survival rates (50). Stason and Barnes note that while there is a lack of systematic comparative data on hemodialysis, the CAPD figures do give cause for concern about the modality's long-term viability (86).

COSTS OF TREATMENT MODALITIES

From an economic perspective the choices made could have important effects on costs. Various studies suggest that there are important differences in costs among modalities, but the estimates offered do not always agree (14,15,31,55,79,86). Table 3 presents estimates from various sources. On balance, in-center hemodialysis is the most costly modality. Within this category, hospitals incur greater costs than independent centers. Home hemodialysis appears less costly than CAPD, except in the Stason and Barnes (86) estimates from Medicare data.

There are various problems with such estimates. For one thing, data are limited in breadth of coverage and depth of detail. Moreover, the choice of modality does vary with age, race, and sex (86). These and other factors create case-mix differences that affect the cost estimates. Cost estimates are also hard to arrive at because assessing certain of the costs is difficult. For example, the costs of home hemodialysis are probably understated because the economic cost of unpaid aides who assist in dialysis is usually not adequately accounted for. Some estimates for CAPD have tried to account for costs of hospitalization (such as would be associated with peritonitis), but other costs are more difficult to incorporate into the estimates. For example, the costs of failure on CAPD, as measured by costs of the resulting change in modality, are higher than for center hemodialysis (86).

On balance, evidence of the cost differences between hemodialysis in hospitals and free-standing facilities is strong. However, a recent assessment for OTA concludes that evidence of other cost differences remains rather uncertain and worthy of further study (86).

Table 3.—Estimated Costs of Dialysis per Patient-Year by Modality (dollars)

Modality	Cost audits (1980-81)		Medicare data		Market study
	HCFA	GAO	1979	1981-82	1981
Center hemodialysis:					
Hospital center	21,060	—	23,562	20,257	28,800
Independent center	16,848	—			24,100
Home hemodialysis	13,572	16,068	18,629	14,485	14,850
Continuous ambulatory peritoneal dialysis	17,784	17,160		10,584	18,300

KEY: HCFA—Health Care Financing Administration, U.S. Department of Health and Human Services; GAO—General Accounting Office.

SOURCES: Cost audit data are presented in W. B. Stason and B. A. Barnes, "Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD) in Comparison With Home and Center Hemodialysis," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, in press; estimates from Medicare data for 1979 are from P. W. Eggers, End-Stage Renal Disease Program, 1983, unpublished, and for 1981-82 are from Stason and Barnes; market study data are from Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981).

3.
Equipment Requirements

3. Equipment Requirements

THE MARKET OVERALL

Of the treatment approaches discussed above, hemodialysis has perhaps the greatest requirements for equipment and supplies. Transplantation, of course, requires the various equipment and supplies associated with the operating room, but the equipment is employed once per transplant and, for the most part, will be used in other surgical procedures as well. Peritoneal dialysis has relatively modest equipment requirements overall. Machinery in the form of dialysate exchange equipment is used in intermittent peritoneal dialysis (IPD) and continuous cycling peritoneal dialysis (CCPD). In the more popular continuous ambulatory peritoneal dialysis (CAPD), considerable use is made of the disposable dialysate which, in this treatment, usually comes in a sterile, prepackaged container. Tubing and other miscellaneous supplies are also employed.

The process of hemodialysis involves a range of equipment and supplies. Machinery is required to pump the blood, prepare and deliver the dialysate, and generally monitor the system for safe operation. Water-treatment equipment may also be used, or, alternatively, purified water may be brought in. In addition, dialysate, dialyzers, blood lines, needles, and assorted other items are needed. The industry typically makes a distinction between "equipment," such as the blood pump and delivery system, and "disposables," such as the dialyzers and blood lines, that in principle are disposed of after each use. Those wishing a finer distinction may also distinguish so-called "consumables" from other disposables. Consumables are more specifically used up during hemodialysis and include the dialysate, heparin (drug used to prevent blood clotting), and saline (solution used to prime and rinse the dialyzer). For the most part this case study will employ the former but not the latter distinction.

Table 4 provides estimates of the dollar value of the ESRD market over time. The total U.S. market for equipment and disposables appeared to have been about $500 million in 1983; and based on 1982 estimates, the worldwide market was roughly three times that size (46).

Equipment and disposables for hemodialysis account for the bulk of the market, but this share

Table 4.—Estimated U.S. Market for ESRD Equipment and Disposables by Year ($ million)

	1975	1976	1977	1978	1979	1980	1983[a]
Hemodialysis:							
Dialyzers	$ 72.3	$ 94.4	$112.5	$131.8	$144.2	$153.7	$148.2
Blood lines	18.0	25.4	32.9	40.2	45.5	49.8	53.9
Other supplies	40.0	55.6	71.2	83.7	98.8	114.6	113.9
Dialysate delivery systems and other equipment[b]	14.0	17.0	20.4	23.9	27.5	31.6	39.5
Total hemodialysis	$144.3	$191.9	$237.0	$299.6	$316.0	$349.7	$385.5
Peritoneal dialysis:							
Continuous ambulatory peritoneal dialysis	$ —	$ —	$ —	$ 0.3	$ 3.2	$ 16.6	$ 99.8
Intermittent peritoneal dialysis[c]	10.0	12.5	15.0	16.8	18.5	16.5	9.1
Continuous cycling peritoneal dialysis	—	—	—	—	—	0.2	17.5
Total peritoneal dialysis[d]	$ 10.0	$ 12.5	$ 15.0	$ 17.1	$ 21.7	$ 33.3	$126.4
Total dialysis	$154.3	$204.4	$252.0	$296.7	$337.7	$383.0	$511.9

[a]Projected in 1981.
[b]Includes parts and service.
[c]Includes acute treatments.
[d]Includes equipment costs.

SOURCE: Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981).

has been decreasing over time, primarily because of the increasing popularity of CAPD. The single most important item overall is the dialyzer. Its 1980 sales accounted for 40 percent of the market. For reasons discussed later in this case study, this share is expected to decline.

Dialyzers are an important segment of the market in dollar terms and thus are worthy of some attention. However, this segment of the market is also of special interest because it appears to be especially sensitive to pressure to reduce the costs of the ESRD programs and more generally sensitive to the resolution of some important policy issues. Thus, it can help illuminate many policy issues and effects. Since much of the analysis in this case study will focus on dialyzers, the next section describes this part of the market in more detail.

DIALYZERS

The Dialyzer Market

Dialyzers consist essentially of three basic parts: a compartment for the blood, a compartment for the dialysate, and a semipermeable membrane separating the two. The three principal types of dialyzers—parallel plate, coil, and hollow fiber—differ essentially in how these basic parts are arranged. All three types of dialyzers are generally described by manufacturers as "single-use disposables," but in fact are often reused. The Kiil dialyzer, a type of plate dialyzer, is specifically designed for reuse but its inconvenience has made its popularity quite limited (117).

Although the specific features of the dialyzers vary among manufacturers, each type of dialyzer has certain basic characteristics. Parallel plate, or simply, plate dialyzers consist of a stack of semipermeable membranes sandwiched between support "plates." Blood passes between the membranes while the dialysate passes in the opposite direction through grooves or spaces in the support plate. In a coil dialyzer, blood passes through semipermeable membrane tubing. The tubing is wound around itself, or "coiled," and a supporting screen separates the coils. The dialysate passes at a 90° angle through the space created by the screen. A hollow fiber dialyzer contains thousands of hollow fibers bundled within a compact cylinder. Blood flows through the semipermeable hollow fiber while the dialysate fluid passes outside the fibers (117).

The growth trend in unit sales, or numbers, of dialyzers is illustrated in table 5. The figures show a continuing decline in the rate of growth of dialyzer sales and most recently an absolute decline in sales. The 1983 data were obtained from a source different from that of the other years' data, so comparisons should be made with caution. Nevertheless, the pattern observed is consistent with the view that the market is contracting (79). The principal explanation for this lies in the increase in dialyzer reuse, a subject addressed later in this case study.

Note also the changing mix of dialyzers sold. The hollow fiber dialyzer has clearly come to dominate the market, while the coil dialyzer has declined markedly in use. The plate dialyzer has managed some increase in share, but market

Table 5.—Estimated Dialyzer Unit Sales by Year

	1975	1976	1977	1978	1979	1980	1983
Total units sold (1,000s)	3,585	4,555	5,410	6,130	6,800	7,445	4,400
Share by dialyzer type (%):							
Hollow fiber	19.1%	21.5%	28.9%	39.3%	47.1%	52.5%	70%
Coil	67.0	63.0	54.0	41.4	33.3	26.3	2
Parallel plate	12.4	14.4	16.5	18.9	19.3	21.1	28
Other	1.5	1.1	0.6	0.4	0.3	0.1	—

SOURCES: For 1975-80 data, Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981); for 1983 data, Information Resources International, Inc., *Biomedical Business International*, VI, Mar. 16, 1983.

analysts expect this share to drop somewhat as hollow fibers continue to gain (79).

There appear to be two principal reasons for the hollow fiber dialyzer's gain in market share. First, hollow fiber dialyzers have excellent dialysis performance characteristics. They are small, efficient, and relatively easy to use. Coils, on the other hand, are more cumbersome and difficult to work with and require relatively high blood volumes. Plate dialyzers are generally regarded as much superior to coils but are viewed by some in the market as slightly less efficient than hollow fibers (79).

The second reason for the hollow fiber gain in market share is its relative suitability for reuse. Although all three types can be reused, the hollow fiber dialyzer has come to be regarded as especially suitable for reuse. The hollow fiber dialyzer's advantages arise because, in practicing reuse, it is important to monitor the changing performance characteristics of the dialyzer as it is reprocessed. This dialyzer's characteristics allow for a relatively straightforward determination of the reused dialyzer's efficiency. This is because the dialyzer's ability to perform its function is directly related to the hollow-fiber cell volume, which can be fairly easily and readily measured. In contrast, the membrane used in plate dialyzers is compliant, and simple volume measurements cannot provide a reliable indicator of performance properties (16,22). Furthermore, cleaning plates is difficult to monitor because blood can get caught between the plates. Finally, many simply regard the hollow fiber dialyzer as more "rugged" and able to withstand the reprocessing treatments (120).

Reuse of Dialyzers

To understand the dialyzer's position in the market, it is important to understand the practice of reuse: it occurs when a dialyzer, after its original use, is reprocessed, stored, and then used again on the same patient, often multiple times. The reprocessing generally begins with an initial rinsing of the dialyzer after dialysis. The dialyzer is subsequently cleaned and disinfected or resterilized (117). The actual reprocessing procedure and the number of reuses tend to vary among facilities. However, various medical and industry groups have been developing guidelines for the reprocessing procedure (e.g., see (71) and (77)). These guidelines include a test of the dialyzer's residual functional capabilities after each use. When the dialyzer functions at an unacceptable level, it is discarded. There are apparently no systematic data on the number of reuses actually achieved nationwide. A recent Health Care Financing Administration (HCFA) analysis of the cost savings from reuse assumes five reuses (103). At a recent workshop, one program reported some success in achieving a "target rate" of eight reuses per dialyzer (84).

In any case, dialyzer reuse, although widely practiced, is quite controversial. This section considers some of the major issues surrounding the practice. As a beginning, some of the history of the practice is recounted. Then its cost and medical consequences are discussed.

History of Reuse

Most dialyzers today are labeled by the manufacturer as intended for single use only. They are "disposables." However the practice of using a dialyzer more than once goes back to the early years of dialysis. In 1964, Shaldon and his associates reported a technique for reuse through refrigerating coil dialyzers (83). A technique for reuse of the Kiil dialyzer, aimed at eliminating the need for disassembly and rebuilding, was described in 1967 (70).

In recent years there has been a renewed interest and indeed a growth in the reuse of "disposable" dialyzers. In a well-known study, Deane found that in 1978 about 17 percent of patients were involved with multiple use (23). A 1982 survey by the Centers for Disease Control indicates that 51 percent of patients were dialyzed in centers that practiced reuse (27). In Europe the practice is also followed but on a somewhat smaller scale. Estimates actually show a decline in the percentage of patients reusing disposable dialyzers from about 14 percent in 1975 to 9 percent in 1981 (41). However, this decline is attributable, at least in part, to the marked expansion of the overall patient base. The actual number of patients reusing dialyzers increased over this period.

Whereas in the early years of dialysis the rationale for reuse was largely convenience (13,22), the driving force behind reuse today is a desire for cost savings. Of course, reuse may have medical effects, both positive and negative. An appropriate assessment of reuse must recognize the various factors involved.

Cost Savings

Estimates of the cost savings associated with reuse are illustrated in table 6. The estimates vary from $1,600 to $6,000 per patient per year because of differences in the assumptions underlying them (e.g., with respect to dialyzer prices, labor, and materials costs, etc.) and because of differences in the actual reuse and reprocessing procedures. They also differ in the time periods on which the estimates are based. As a result they may not fully reflect experiences today.

If one assumes a savings of $2,000 per patient per year with reuse and a patient population on reuse of 40,000 (roughly 50 percent of the ESRD population), then the yearly savings amount to $80 million. As the industry has pointed out, savings of this magnitude represent a relatively small portion of ESRD program costs (117). In this hypothetical case the savings are less than 5 percent of program costs. Nevertheless, economies of this magnitude are certainly attractive.

Table 6.—Selected Estimates of Savings From Dialyzer Reuse

Source of estimate	Savings per patient year[a] ($ current)
Fawcett and Mangles (1974)	$3,000
Foxen (1983)[b]	1,900
Hoffstein, et al. (1976)	1,600-2,400
Scribner (1977)	2,500-6,000
U.S. DHHS, HCFA (1981)[b]	2,000

[a]Rounded to nearest $100.
[b]Estimates are for dialyzer reuse without reuse of blood tubing.

SOURCES: B. Scribner, testimony at hearing before U.S. House of Representatives, Subcommittee on Health of the Committee on Ways and Means, Apr. 25 1977; P. A. Hoffstein, et al., "Dialysis Costs: Results of a Sample Study," *Kid. Int.* 9:286-293, 1976; and K. C. Fawcett and M. D. Mangles, "Reuse of the Gambro Lundia 17-Layer Dialyzer," *Dialysis and Transplantation* 3(1):38-40, 1974. Figures are derived from the summary in G. T. Willingmyre, *Reuse of Single-Use Hemodialyzers* (Washington, DC: Health Industry Manufacturers Association, 1979). Data from Fawcett and Mangles (above) and L. G. Foxen, "Is Reuse Cost Effective? A Case Study," in *Reuse of Disposables*, Association for the Advancement of Medical Instrumentation, Technology Assessment Report No. 6-83, Arlington, VA, 1983, were converted from cost savings per treatment by assuming 156 treatments per year. HCFA data are from U.S. Department of Health and Human Services, Health Care Financing Administration, Memorandum on Hemodialysis Reuse from Edward L. Kelly to Carolyne K. Davis, July 31, 1981.

Of course, one might still challenge the validity of such figures. Note that the more spent on reprocessing, the less the cost savings of reuse. Representatives of the dialyzer industry have suggested that with appropriately rigorous reprocessing, savings might be much less than are now envisioned. Although manufacturers are subject to Federal regulations concerning good manufacturing practices (GMP), clinics and hospitals reusing dialyzers generally are not. These regulations, part of the Food, Drug, and Cosmetics Act, mandate minimum quality assurance requirements in the manufacturing or processing of a medical device. If the GMP regulations were to be applied to hospitals and clinics, it is argued that reprocessing might well become more costly (42,43, 44,117).

However, even if clinics and hospitals were to perform reuse according to GMP regulations, the cost of reprocessing, as estimated by one member of the industry, would still allow a saving from reuse (44). As further evidence consider market-generated estimates of reprocessing costs. Multi-Use Systems, Inc., a new private company that reprocesses dialyzers, charges $6.50 per dialyzer for reprocessing, including pickup, delivery, and labeling. The firm uses automated reprocessing equipment and, according to the firm, follows careful and rigorous procedures (24). With the assumption of five reuses and a new dialyzer price of $20, savings per patient year for the facility would come to roughly $1,800 and would still presumably allow a profit for the reprocessing company.

Medical Consequences

Of course, any estimates of cost savings must rest on a medical assessment of reuse. If reuse were medically harmful to patients, then the costs of increased morbidity or mortality would probably dwarf the direct cost savings associated with it. Thus, an appropriate assessment must be based ultimately on considerations of the practice's clinical safety and effectiveness.

Various concerns have been expressed about the possible negative medical effects of reuse (e.g., see (43)). However, others have suggested that reuse may actually have some salutary effects. A. Peter Lundin (54) has offered a summary of "presumed

and proven" medical indications and contraindications for reuse. These are presented in table 7. There are bits and pieces of evidence in support of these items, but the consensus of a recent National Workshop on the Reuse of Consumables in Hemodialysis concludes that overall there is only "a small but finite risk of morbidity and negligible or no risk of mortality with reuse in the immediate treatment setting" (77).

In coming to such a conclusion, workshop participants also pointed out that the safety and effectiveness of reuse depends on appropriate reprocessing standards. They also recognized that the long-term risks are unknown. Accordingly, the consensus statement urges further study of the potential medical effects of reuse.

In an assessment of reuse, there is often a tendency to ignore the patient's perspective. Patients face the issue from their own special perspectives (see, e.g., (54) and (62)). They recognize the desirability of cost savings in the ESRD program and are even attracted by potential benefits such as the prevention of new dialyzer syndrome, a possible negative reaction to using new dialyzers resulting in respiratory distress, wheezing, back or chest pain, chills, or fever (67). Yet they are concerned about the presently unknown long-term risks and emphasize the need for more scientific study.

In considering the patient's position, one should note that the cost savings from reuse or the costs of complications from reuse do not all accrue to patients. Medicare, the dialysis facility, and patients can all be affected, and each group can have its own perspective and incentives. Ethicist Arthur Caplan (18) notes that the dialysis patient, by virtue of his or her illness, may be particularly "vulnerable." He argues strongly that the ethics of therapy require that patients be informed fully about reuse and allowed to consent or not consent to the practice.

Table 7.—Suggested Medical Effects of Reuse

Medical contraindications to reuse	Medical indications for reuse
1. Induction of hypercoagulability.	1. Prevention of new dialyzer syndrome.
2. Requirement of larger heparin doses.	2. Less accumulation of manufactured residuals.
3. Formation of anti-N-like antibodies.	3. No other way to avoid problems (1) and (2).
4. Formation of other auto-antibodies.	4. Equivalency or superiority to single dialyzer use.
5. Toxic effects of disinfectants.	
6. Lack of strict standards.	
7. Inferiority to single dialyzer use.	

SOURCE: A. P. Lundin, "Economy at Whose Expense: The Ethics of Dialyzer Reuse and Informed Consent," in *Reuse of Disposables*, Association for the Advancement of Medical Instrumentation, Technology Assessment Report No. 6-83, Arlington, VA, 1983.

4.
Market Structure and Competition

4. Market Structure and Competition

A market consists of a group of buyers and sellers coming together to exchange a product or service. That interaction helps determine the product's prices, quantities, and quality. To understand how these items are determined, and to evaluate the economic performance of the hemodialysis equipment and disposables industry, it is important to understand how buyers and sellers are organized and how they compete. This section addresses the question of market structure both from the seller's side and the buyer's side; and since the U.S. market is not independent of foreign markets, the international features of the market are also examined.

THE SELLERS

Market Concentration

A key feature of any market is its degree of competitiveness. One factor that characterizes competitiveness is market concentration, the degree to which overall market activity is distributed among (or concentrated within) the firms in the market. Economic theory suggests that the degree of competition is related to market concentration and, in particular, that competition may be stifled when a small number of firms controls a large share of the market activity.

Evidence on market concentration in the industry is presented in tables 8 through 11.[1] Tables 8 and 9 offer data on firms' shares of sales of dialysis equipment and disposables. Table 8 focuses on sales to hospitals only, whereas table 9 presents estimates for the market overall. Sim-

[1]Data on hospital purchases come from an ongoing survey conducted by IMS America. Data on the market overall are derived from published estimates by professional market analysts. Although such estimates are generally respected, the sources and methods by which they are generated are proprietary and cannot be subjected to an objective evaluation of reliability.

Table 8.—Estimated Shares of U.S. Hospital Market for Dialysis Equipment and Disposables by Year (percent)

	1977[a]	1978	1979	1980	1981	1982	1983[b]
Baxter Travenol	32.7%	23.4%	29.4%	28.4%	26.6%	30.0%	29.4%
CD Medical Inc. (Cordis Dow)	19.2	19.0	20.1	15.5	22.5	27.1	22.4
Extracorporeal[c] (Johnson & Johnson)	16.5	20.0	14.4	22.8	18.6	10.4	10.8
Gambro AB	15.1	12.7	9.4	10.4	11.1	13.9	13.3
Cobe Labs	5.0	12.1	13.3	10.0	7.6	7.2	7.2
Organon-Teknika	1.7	1.8	1.9	2.6	2.0	1.5	(d)
Warner Lambert	1.7	1.7	(d)	(d)	(d)	(d)	(d)
Bentley (American Hospital Supply)	1.5	(d)	(d)	(d)	(d)	(d)	(d)
Becton Dickinson	(d)	4.6	3.2	(d)	(d)	(d)	3.9
Erika	(d)	(d)	2.4	2.0	4.7	1.7	2.7
Vernitron Corp.	(d)	(d)	(d)	2.0	2.0	(d)	(d)
Terumo-America, Inc.	(d)	(d)	(d)	(d)	(d)	1.7	3.1

[a]Based on last 6 months of 1977.
[b]Based on first 5 months of 1983.
[c]Includes very small portion of sales attributable to Critikon Division of company.
[d]Not among leading eight corporations in this year. Figures not available separately.

SOURCE: Compiled from survey by IMS America, Ltd., Hospital Supply Survey, contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

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Table 9.—Estimated Shares of Total U.S. Market for Dialysis Equipment and Disposables by Year (percent)

	1975	1976	1977	1978	1979	1980	1983[a]
Baxter Travenol	32.7%	22.7%	22.1%	21.9%	24.0%	26.3%	34.9%
CD Medical Inc.	11.0	12.4	14.1	14.9	15.5	13.6	9.1
Cobe Labs	8.4	7.8	8.9	10.7	11.8	12.3	10.8
Extracorporeal	9.8	9.7	9.1	7.9	9.2	10.0	8.9
Erika	2.6	4.0	5.4	6.1	6.4	7.9	13.1
Gambro AB	6.5	6.5	6.3	6.5	6.9	2.3	5.7
Becton Dickinson	2.6	2.5	2.5	2.9	2.8	3.0	3.0
Renal Systems	0.6	1.0	1.5	2.0	2.2	2.3	2.7
Terumo-America, Inc.	—	0.7	1.2	1.7	2.1	1.7	1.3
Bentley	1.0	1.5	1.9	1.4	1.0	0.8	—
McGaw	1.9	2.0	1.8	1.7	1.5	1.1	1.6
Abbott	—	—	—	—	—	—	2.4
All others	22.9	29.3	25.1	22.5	16.6	13.7	6.5

[a]Projected by Bernstein in 1981.

SOURCE: Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981).

ilarly, tables 10 and 11 present data on relative shares for dialyzers alone, considering again, respectively, hospitals and the market overall.

The evidence in the tables presents a consistent picture, with Baxter Travenol emerging as the U.S. leader. CD Medical, Inc., Gambro AB, and Extracorporeal are also key firms. (For brief descriptions of the major firms in the industry see app. A.) In order to assess the competitive implications of this pattern, analysts often use a single "summary" measure that can be used for comparative purposes. Two of the most commonly used measures of market concentration are considered here: the four-firm concentration ratio and the Herfindahl index.

The four-firm concentration ratio measures the total market share of the largest four firms in the industry. Where this ratio is high, competition is likely to be less intense, since the largest firms may have a greater opportunity to exercise market power (80). In the hospital market for equipment and disposables (table 8), the concentration ratio was 76 in 1983. The ratio is slightly lower, 68, in the market overall (table 9). In the hospital market for dialyzers (table 10), the ratio was over 90 in 1983. For dialyzers overall, the ratio was 79. Although the concentration ratio is an imperfect measure of competition, the figures for the industry put it at or in excess of the 60 to 70 percent figure often viewed as the threshold for possibly serious competitive problems (80). Furthermore, this situation appears to have persisted over the past several years.

An alternative measure of market concentration is the Herfindahl index. It is generally regarded as superior to the concentration ratio (80), but it is less widely used because the data for its calculations are often not available. It is calculated by summing the squared values of the market shares of the firms in the industry. Calculating shares in fractional or decimal terms, the index can range in value from near zero, for an industry composed of many small firms, to one, for a monopoly. Again, economic analysis indicates that where this value is higher, the scope for anticompetitive behavior increases.

From the data in tables 8 through 11, Herfindahl indices can be calculated. In 1983, they ranged from about 0.16 to 0.17 for all dialysis equipment and supplies and from 0.17 to 0.28 for the dialyzer market. Since data limitations have restricted use of this index in economic studies, there is little basis for comparison among industries. However, recently published guidelines from the Department of Justice use the index in explaining their attitudes toward proposed mergers. Markets with index values in the range observed for the dialyzer market (greater than 0.18) are characterized as "highly concentrated." In such markets, mergers that increased concentration to such levels would be a "a matter of significant competitive concern" (104).

Entry

Another important characteristic of an industry's structure, and its competitiveness, is the condition of entry. Is entry into the industry fairly

Table 10.—Estimated Shares of U.S. Hospital Market for Dialyzers by Year (percent)

	1977[a]		1978		1979		1980		1981		1982		1983[b]	
	Dollars	Units	Dollars	Units	Dollars	Units	Dollars	Units	Dollars	Units	Dollars	Units	Dollars	Units
Baxter Travenol	33.0%	23.9%	24.2%	19.1%	33.7%	34.1%	32.4%	31.6%	31.3%	30.6%	37.9%	38.1%	40.1%	43.0%
CD Medical Inc.	25.5	22.0	25.1	16.7	25.6	20.8	19.5	17.7	26.2	24.3	31.1	31.2	26.0	24.2
Gambro AB	20.9	33.9	17.3	25.3	11.5	13.1	12.9	12.5	13.4	12.7	15.8	14.0	15.8	13.8
Extracorporeal	14.4	16.0	18.9	25.3	11.2	13.8	23.0	25.8	18.4	22.5	8.6	10.6	10.6	12.5
Bentley	2.2	2.6	0.6	0.8	0.2	0.3	0.2	0.3	0.1	0.1	(c)	(c)	(d)	(d)
Cobe	1.5	0.2	9.6	9.0	11.8	12.1	8.5	8.7	4.6	4.6	4.3	4.1	3.1	2.4
Becton-Dickinson	1.1	0.8	3.7	3.5	2.0	1.7	(d)	(d)	(d)	(d)	(d)	(d)	(d)	(d)
Erika	1.1	0.6	0.4	0.4	2.7	3.3	2.2	2.1	5.6	5.0	1.6	1.3	1.6	1.4
Hospal	(d)	(d)	0.1	0.1	1.3	0.8	0.4	0.2	0.2	0.1	0.1	(c)	(c)	(c)
Terumo-America, Inc.	(d)	(d)	(d)	(d)	(c)	(c)	0.9	1.1	0.1	0.1	0.6	0.6	2.5	2.6
Organon-Teknika	(d)	(d)	(d)	(d)	(d)	(d)	(d)	(d)	(c)	(c)	(d)	(d)	0.2	0.2
All others	0.3	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

[a]Based on last 6 months of 1977.
[b]Based on first 5 months of 1983.
[c]Very small sales (less than 0.1%) indicated in survey.
[d]No sales indicated in survey.

SOURCE: Compiled from survey by IMS America, Ltd., Hospital Supply Survey, contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

Table 11.—Estimated Shares of Total U.S. Market for Dialyzers by Year (percent)

	1975	1976	1977	1978	1979	1980	1983
Baxter Travenol	47.4%	41.1%	34.1%	33.1%	30.9%	29.3%	26%
CD Medical Inc.	18.7	18.6	21.3	24.5	27.9	23.5	20
Extracorporeal	18.8	16.9	14.9	11.0	10.8	12.5	NA
Gambro AB	11.2	11.0	10.9	10.9	10.9	12.1	24
Cobe	0.4	1.9	5.2	8.1	8.9	9.6	9
Erika	0.4	4.2	6.9	7.7	7.7	9.4	7
Bentley	1.1	3.7	4.2	3.0	1.9	1.5	NA
Hospal	—	—	0.1	0.2	0.2	0.9	NA
Terumo-America, Inc.	—	—	—	—	—	0.7	9
Organon-Teknika	—	—	—	—	0.1	0.2	NA
Renal Systems	—	—	—	—	—	0.1	NA
Renal Devices	—	—	—	—	—	0.1	NA
All others	2.0	2.6	2.4	1.5	0.7	0.1	NA

NA indicates data not available.

SOURCE: For 1975-80 data, Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry* (New York: February 1981); for 1983 data, Information Resources International, Inc., *Biomedical Business International*, VI, Mar. 16, 1983; and A. Kraus, Executive Vice President, Gambro AB, personal communication, September 1983.

easy or are there substantial "barriers" to new firms? If substantial barriers do exist, established firms are insulated from an important source of competition, the new entrant.

Barriers to entry arise from the advantages established firms have over new entrants. These could include cost advantages associated with access to technology or materials, or "product differentiation" advantages associated with the strong image of established producers with customers. Certainly some of these advantages exist. Firms such as Baxter Travenol, for example, have established a strong identity with buyers. Cordis Dow for many years controlled patents in hollow fiber dialyzer technology and, although they have extensively licensed them to other firms, this may have generated some cost advantages for the company.

An indirect test of the condition of entry can be performed by observing actual patterns of entry. If entry can be accomplished relatively easily and the market offers profit potential, then entry should occur. A review of tables 8 through 11 suggests the emergence over time (i.e., the movement from unmeasured to significantly measurable sales) of at least a few firms. Most notable are Terumo America and Abbott Labs. Each emerged from a solid base: Abbott moved into dialysis from a strong foothold in related health markets; Terumo America is part of a large Japanese firm that produces dialysis products. Upon entry to the U.S. market the company was accused of infringing on Cordis Dow patents. The suit was settled when Terumo agreed to royalty payments (79).

In the dialyzer market, in particular, one sees a number of new entrants. However, other than Terumo, none has managed to achieve a major market share. Another form of entry has occurred among some of the existing dialyzer producers, who are now making hollow fiber dialyzers. Extracorporeal, a producer of coil dialyzers, began to produce hollow fiber dialyzers in 1977. Similarly, Erika moved into hollow fibers in 1980, and Gambro entered in 1979 (61,79). These companies already had a part of the overall market, so such entry was easier than it would have been de novo.

Although the evidence suggests that some entry into the dialysis equipment and supplies market is possible, it is hardly wide open. Entry has mainly consisted of established firms expanding geographically (e.g., from Japan to the United States) or into related products (e.g., into production of another type of dialyzer). Another indication of the difficulty of entry is the degree of stability in the identities of the major firms. The lack of opportunity to move within the market is also a sign of some limits in competition (see, e.g., (19)). Overall, therefore, the market may best be characterized as having moderate barriers to entry.

THE BUYERS

The ultimate consumers of hemodialysis equipment and supplies are, of course, the patients on hemodialysis. However, for the most part, the buyers in this market are the various facilities, hospital-based and free-standing, offering dialysis services. Facilities purchase equipment and supplies from manufacturers; patients then pay facilities a rate per dialysis session. The exception to this occurs primarily in the case of home dialysis. A recent study by the U.S. General Accounting Office (GAO) found that about 70 percent of home patients were dealing directly with suppliers (105). For the remainder, the contact with suppliers was accomplished through the dialysis facilities. The hospitals and patients do not constitute a highly concentrated buying group. Hospital-based facilities, for the most part, seem to make purchases independently of one another. Although some facilities may be quite large, power over price will depend on the hospital's ability and willingness to bargain with suppliers.

Individual patients on home dialysis have even less power given the proportionately smaller quantities purchased. However, given the existence of coinsurance, the patient has a personal incentive to bargain. Note also that many of these patients lease rather than purchase, but GAO has suggested that a switch to purchasing may be cost effective (105).

The greatest market power on the buyers' side probably rests with free-standing facilities. These facilities account for a growing share of the market. As of 1981 approximately 42 percent of facilities were independent. The comparable figure was 11 percent in 1973. Such facilities are predominantly profit-making enterprises and are larger on average than hospital facilities (110). Their power and incentives are accordingly likely to be greater. The key example here is National Medical Care, Inc. (NMC). With its 161 facilities it can potentially exert a great deal of pressure on sellers. NMC does have a substantial portion of its supply needs met by its own subsidiary, Erika.

Another major purchaser is the Veterans Administration (VA), which was an early supporter of dialysis treatment for its clientele. The VA accounts for roughly 3 percent of treatment volume in the United States (79). GAO suggests that the VA has used its market power effectively to secure more favorable terms of purchase (105). Smaller units might, of course, enhance their market power if they were to form cooperative buying groups. GAO has even suggested that this might be accomplished under Federal Government auspices.

INTERNATIONAL DIMENSIONS

The market for hemodialysis equipment and supplies is clearly international in scope. In the United States alone, foreign-owned firms have become increasingly important. The most important of such firms is probably Gambro, which is incorporated in Sweden. Gambro produces various products and overall is the world's leading manufacturer of dialysis equipment and disposables (61).

Terumo has become a significant competitor, although still a relative newcomer to the U.S. market. Its success seems to stem largely from an aggressive pricing strategy (79), even though it does not manufacture dialyzers in the United States.

Other foreign-owned firms have also played a role in the U.S. market. As noted in tables 10 and 11, foreign-owned firms such as Hospal and Organon-Teknika participate in the dialyzer market. Still others can be expected to initiate or step up activities here. For example, Toray, a Japanese manufacturer of hollow fiber dialyzers, is reported to be planning marketing efforts in the United States (39).

This interest is not surprising. Particularly in the 1970s, the U.S. market showed dramatic growth and appeared quite attractive. The U.S. population of ESRD patients is still large and generates roughly one-third of the world market (46).

Thus, it remains an attractive market for world producers. Despite current competitive pressures in the U.S. market, foreign firms with an established market base elsewhere may be able to compete effectively here.

At the same time, U.S.-based firms have ventured into foreign markets. Many foreign countries are experiencing greater increases than the United States in the patient population, and these foreign markets are quite attractive (46,50). Table 12 illustrates the U.S. role in a number of markets for renal equipment. The variations observed seem attributable to numerous factors. Historical, geographic, political, and economic factors probably all contribute. In any case, U.S. firms clearly are playing an important role abroad. Although market shares in some countries may decline as the markets expand, the potential sales remain a strong attraction.

The U.S. firms' movements into foreign markets is consistent with a general pattern in U.S. manufacturing, particularly in so-called "high-tech" industries. Most observers have tended to view this as an attempt to take advantage of the technological superiority of the firms' products. (For example, see (32), (37), (111), and (112).) Whether this superiority existed in this market is unclear. Certainly today, leading foreign firms seem to produce products of comparable quality. Indeed, as noted above, foreign firms have made inroads into the U.S. market.

If one judges from the dialyzer market, technological factors have been of some importance domestically and internationally. Cordis Dow's power in the dialyzer market stemmed at least in part from its control of patents related to the hollow fiber dialyzer. Erika's production of hollow fiber dialyzers in Ireland is being done through licensing technology from a foreign firm, Fresenius (39). Many dialyzer manufacturers use a membrane, Cuprophan, which is made by Enka, a West German company, although Japanese and other foreign and U.S. firms are developing membranes as well (2).

International activity may also be prompted by a production technology that may involve significant economies of scale in dialyzer production (47,79). These economies may prompt firms to broaden their market to achieve further sales and to maintain or achieve potentially lower unit costs. Economies of scale would allow Terumo, for example, operating from a high-volume base in Japan, to export to the U.S. market at a competitive price. Economies of scale may also lead firms with declining domestic sales to seek markets abroad, thereby allowing high-volume production to be maintained.

Table 12.—U.S. Involvement in the Renal Equipment Market in Various Countries

Country	Year	Total sales ($ millions)	Imports from U.S. ($ thousands)	U.S. market share (%)
Belgium	1979	$5.3	$583	11%
	1985[a]	6.4	750	12
Germany	1979	12	2100	17.5
	1985[a]	28	3000	11
Mexico	1980[a]	4.3	3500	81
Philippines	1979	0.48	251	52
	1985[a]	0.80	443	56
Spain	1978	5.31	1850	35
	1983[a]	8.0	1600	20
Switzerland	1979	2.1	900	43
	1985[a]	2.5	1200	48
Taiwan	1978	0.15	150	100
	1983[a]	0.8	200	25
United Kingdom	1979	21.6	2530	12
	1985[a]	26.0	2500	9.6

[a]Estimated

SOURCE: U.S. Department of Commerce, International Trade Administration, Country Market Survey, *Medical Equipment, Belgium*, CMS 82-517, February 1982; idem, *Medical Equipment, Germany*, CMS 82-516, February 1982; idem, *Medical Equipment, Mexico*, CMS 79-004, February 1979; idem, *Medical Equipment, Philippines*, CMS MED 565/83, March 1983; idem, *Medical Equipment, Spain*, CMS 81-511, September 1981; idem, *Medical Equipment, Switzerland*, CMS 81-512, September 1981; idem, *Medical Equipment, Taiwan*, CMS 81-509, February 1981; idem, *Medical Equipment, United Kingdom*, CMS 81-515, September 1981. Renal equipment as defined appears to include at least some disposables.

5.
Industry Performance

5. Industry Performance

Industrial economists generally expect an industry's structure to have an important influence on the industry's behavior and its quality of economic performance. This performance is generally gauged in terms of the efficiency with which resources are allocated and utilized. From a policy viewpoint, good performance is the ultimate objective, and policies that can improve that performance become attractive. This section discusses some of the key features of the industry's economic performance.

PRICES AND PROFITS

As a guide to economic performance, economists often focus on prices and profits. Low prices are attractive to consumers. Prices and costs together determine a firm's profits. Profits, although the logical reward to successful business activity, can arise for a variety of reasons. For example, successful innovation or unexpectedly large increases in demand for an industry's product could lead to high profits, at least for some period of time. However, when profits are much higher than investors are earning in other parts of the economy, it may signal monopoly power. Such power imposes costs on consumers, via high prices, and on the society at large, via inefficient utilization of society's resources (see (80)).

Analysis of market prices and profits is complicated by a variety of factors, including various sorts of data limitations. For example, some price data may be available, but these published prices are list prices and do not necessarily reflect the transaction prices, which are often discounted from list price. Even if transaction prices were available, comparisons over time would require adjusting for changes in the nature of the products being sold. Technological improvements and various other modifications make the specific list of products sold today different from those sold several years ago.

Profit data are also not generally available through published sources. Firms that are not publicly held are not subject to the disclosure rules of publicly held corporations. Foreign-owned companies also pose special difficulties. Even in cases where there is public disclosure, profits on hemodialysis equipment and disposables may be difficult to ascertain. As noted in appendix A, many of the firms in the industry operate in a variety of markets. Although the Securities and Exchange Commission does require some product line breakdowns of sales and profits, the breakdowns are generally too broad (e.g., "medical care products") to allow for assessment of this market in particular.

Surveys can overcome some but not all of the above limitations. In its study of ESRD equipment and supplies, Orkand Corp. (68) notes various difficulties in estimating prices, but seems to conclude that prices have, in general, shown little upward movement and, indeed—after adjusting for inflation—have actually declined. For dialyzers, it concludes that the decline has been especially notable.

The discussion of prices here concentrates on dialyzers since they have been a principal concern of this case study and price data for this market are relatively easy to interpret. The IMS America survey referred to earlier provides data that allow for the calculation of the average price paid for dialyzers by hospitals. These data are presented in table 13.

The results are rather remarkable. Prices, even in current dollar terms, have fallen over the past 5 years. After adjusting for inflation, the overall decline is approximately 34 percent. Furthermore, this decline in real prices seems to exist for all kinds of dialyzers. For example, Baxter Travenol's hollow fiber dialyzers and the dialyzers of CD

Table 13.—Average Prices for Dialyzers Purchased by Hospitals From Major Producers by Year[a] (current dollars)

Company and dialyzer	1978	1979	1980	1981	1982	1983[b]
Baxter Travenol[c]	$25.4	$23.1	$24.3	$23.4	$21.7	$17.9
Hollow fiber	27.7	25.0	26.2	24.6	22.0	17.9
Coil	23.9	20.3	20.1	19.5	19.5	23.5
Parallel Plate	31.5	32.7	—	—	—	—
CD Medical Inc. (Cordis Dow)	30.2	28.6	26.1	24.6	21.7	20.7
Gambro AB	(e)	20.4	24.4	24.0	24.7	22.3
Extracorporeal	(e)	18.9	21.1	18.7	17.6	16.3
Bentley	(e)	16.6	16.4	16.2	NA	NA
Cobe Labs	21.5	22.7	23.3	23.2	22.5	24.8
Becton Dickinson	21.6	27.6	18.8	NA	NA	NA
Erika	21.5	19.0	25.1	25.7	26.5	21.6
Hospal	43.0	37.6	38.0	37.6	34.3	34.0
Terumo-America, Inc.	NA	27.0	19.1	25.4	NA	18.5
Organon-Teknika	NA	NA	NA	10.9	NA	NA
Grand average[d]	20.1	23.3	23.7	22.9	21.8	19.2
Grand average (adjusted for inflation)[d f]	20.1	21.0	18.8	16.6	15.2	13.2

NA indicates data not available.
[a]Prices are calculated as dollars sales divided by total units sold.
[b]Based on first 5 months of 1983.
[c]Data for Baxter Travenol allowed for computation overall and by dialyzer type. Prices for other companies may include a mix of types of dialyzers.
[d]Computed from total sales to sample hospitals of all types of dialyzers from all companies.
[e]Data did not allow for meaningful calculations.
[f]Adjustment to 1978 prices is based on the producer price index for finished goods. Values of price index for 1983 is value for June 1983 (U.S. Department of Commerce, Bureau of Economic Analysis, *Business Statistics: 1982*, 23d ed., November 1983; and U.S. Department of Commerce, Bureau of Economic Analysis, *Survey of Current Business*, November 1983).

SOURCE: Computed from data in IMS America, Ltd., Hospital Supply Survey, contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

Medical (which focuses on the hollow fiber) show an average decline of about 56 percent, after adjusting for inflation (and weighting by their relative sales). Prices of Baxter Travenol's coil dialyzers also show a decline in real terms of 32 percent. And prices of plate dialyzers have probably also fallen. Data are not separately available, but the two leading manufacturers of plate dialyzers, Gambro and Cobe (79), both experienced price declines, once an adjustment is made for inflation. Although these figures are based on prices paid by hospitals, the results are consistent with general business assessments of price movements (39,68,79).

For reasons alluded to earlier, the profit consequences of this price decline are not easily assessable. Profits for dialyzers are rarely singled out, although some assessments of profitability do exist. A 1983 evaluation of Baxter Travenol stock contends that the company is making good profits on hollow fiber dialyzers (47). CD Medical (formerly Cordis Dow), on the other hand, has been experiencing losses overall for the last 3 years; this appears at least partly due to its hollow fiber dialyzers (17,59,114,115).

Overall, however, the major companies remain viable. In part this is because they have been able to lower production costs (47). Profit margins have apparently declined, but as noted earlier, over the past few years, some new entrants have found the potential sufficient to entice them into the market.

Given the description of market structure provided earlier, the downward movement in prices and, apparently, in profits requires some further explanation. The market as described has been one of high seller concentration and generally low buyer concentration. This may help explain the attractive profits earned several years ago (79). But the measured market concentration of sellers has not evidenced a decline that might explain a fall in prices. Clearly other factors must have been at work.

One likely source of the price problem for manufacturers is the unduly optimistic past expectations about the growth in the market. When profit prospects were good, capacity was expanded, especially in the production of hollow fibers. Yet, the rate of growth in unit sales of dialyzers has

been falling over the past several years, both overall and for hollow fiber dialyzers in particular (see table 5 in ch. 3; also, (79)). Indeed, unit sales of hollow fibers have actually shown a decline in the past year. The result is extensive overcapacity in the industry (47,79). The overcapacity led to price cutting as manufacturers strove to maintain output and share in a decelerating and finally shrinking market.

The major factor that slowed the growth in dialyzer demand was the growth in reuse. As reuse increased, the number of new dialyzers required per patient fell. With demand failing to keep up with supply, it was inevitable that there would be downward pressure on prices—even in this concentrated market. A 1981 market survey notes that "market share has lost much of its traditional significance. . . . Dialyzers have become a pure, price-sensitive commodity for which prices determine share" (79).

Buyers have contributed to reaching this outcome. Although they had little concentrated market power, buyers were both prepared and motivated to take advantage of the manufacturers' dilemma. Buyers, too, have been under pressure—in this case from Federal Government insurers—to control the costs of treatment. Reuse was one potential source of cost savings. More active bargaining with suppliers was another.

There is some support for the notion that buyer pressures to reduce prices may matter. That lies in the diversity of prices paid by various buyers. GAO, for example, notes in its survey that Medicare paid $12.70 more per dialyzer session for supplies than did the Veterans Administration (105). Informal discussions with users and various market surveys suggest that prices of new dialyzers may vary considerably among customers (79). The data in table 13, which show some variation in actual prices, despite relative stability in official list prices, support such a view (68). Thus, there appears to be some scope and potential for bargaining by buyers.

PROSPECTS FOR THE INDUSTRY

Prospects for Prices and Profits

Market prospects depend to a great degree on technological, medical, and policy developments. Over the next few years the dialyzer market seems likely to continue to contract (47,79). Two factors should contribute to this decline. One is a continued growth in reuse of dialyzers. The other is the likely growth in alternative treatment modalities.

As noted earlier, reuse has been growing in the United States. Given the cost savings associated with reuse and the current consensus that reuse is indeed safe when proper procedures are followed, this growth will probably continue. The ultimate extent of the practice is difficult to assess. Although statistics for Europe show some decline over time in the percentage of patients reusing dialyzers, these statistics are based on an expanding patient base and may reflect additional single-use cases rather than any discontinuation of reuse (41). Certainly, there is room for further increase in reuse in the United States.

The dialyzer market will also be affected by expected changes in the mix of treatment modalities for patients with ESRD. Most projections show a slowed rate of growth in the number of patients on dialysis (46,79). If transplantation possibilities improve, this growth will be further slowed. On the other hand, any broadening of the criteria for placing patients on dialysis would increase the patient population.

Within the dialysis population there is likely to be continued movement toward continuous ambulatory peritoneal dialysis (CAPD). A recent investment study predicts that 19 percent of the population will be on this modality within the next 3 years (46). Other treatments such as hemofiltration may also gain in popularity. Hemofiltration involves separating a patient's blood, by filtration rather than dialysis, from fluids bear-

ing waste products. The fluids are then replaced by other sterile liquids. The process is less time-consuming and is apparently better tolerated by some patients (61). As of 1982 about 1.6 percent of European patients were on hemofiltration (50). One study suggests that if technical problems associated with cost efficient replacement of fluids are solved, hemofiltration could account for as much as 30 percent of the world market within 5 years (4).

This combination of factors points to continued downward pressure on the demand for new dialyzers. This pressure may be particularly acute for coil dialyzers, which seem likely to continue their marked decline. Sales of parallel plate dialyzers, although generally superior in performance to coils, will also likely decline, mainly because of a continuing preference for hollow fibers. The hollow fiber dialyzer, because of its performance properties and its attractiveness for reuse, should continue to dominate the market. One study judges this the "only viable dialyzer market segment" (79). It probably will fare the best among dialyzers but still suffer declines in absolute volume.

These factors, along with continued buyers' concern for cost control, should maintain prices and profit margins at their present apparently low level. Many observers expect this pressure to lead to a "shakeout," with weaker firms forced from the industry (46,79). To the extent that overcapacity and competition are reduced, a shakeout could lend support to prices. Some suggest that the result might be a return to higher, monopoly-like prices (35). Although the high degree of market concentration suggests potential ability for tacit price coordination, the probability of a move to near-monopoly prices seems low. The adverse demand conditions, the potential opportunities (albeit perhaps only moderate) for entry, and the diverse character of firms and their objectives, all would work against such an occurrence (80). Continued reductions in production costs would further contribute to anti-monopoly pressures (79).

New Directions for the Companies

Although the dialyzer market shows reduced profit potential, other segments of the market seem to be attracting considerable interest among manufacturers. Discussions with members of the industry, as well as studies by investment firms, suggest a number of areas where substantial potential exists, particularly in peritoneal dialysis, and especially in CAPD.

Although there is still a great deal of clinical uncertainty about CAPD, most observers, as noted earlier, are expecting an increase in its use. At present the market is dominated by Baxter Travenol, which in 1982 had more than 90 percent of market sales (46). Profit from these sales appears quite high. One report estimated the company's profit in 1982 to be $80 million on $100 million of sales of CAPD solutions and supplies (39). Evaluations of the company's stock cite its presence in the CAPD market as a key reason for optimism about the company's future prospects (5,46,47). Such potential has not gone unnoticed by other companies. For example, Abbott Labs is making strong efforts, and firms such as Gambro, which are established in hemodialysis, are entering the CAPD market as well (5,61).

Much of the success of the CAPD market may depend on technological development. While research continues on the effectiveness of the modality, manufacturers are trying to develop sterile connection devices aimed at lessening the incidence of peritonitis, a major concern with CAPD (4,46). Although uncertainties about the scope of the market abound, it is likely that this sector will become increasingly competitive.

Just as one response to the threat posed by CAPD is to enter that part of the market, companies may respond to reuse by entering the market for automated dialyzer reprocessing equipment. The success of such equipment will depend not only on its efficiency but on the ultimate course of dialyzer reuse. However, companies in

this field may also be attracted by potential in other markets where "disposables," such as catheters, are also reused. A recent business publication lists a number of companies in the field (39). Only one, Renal Systems, actually showed up as a seller in tables 8 to 11 in chapter 4, and its sales are quite small. However, such a market would constitute a natural extension for dialyzer manufacturers.

Another major area of interest is hemofiltration. As noted earlier, some analysts expect this treatment to become increasingly popular. Gambro has shown particular interest here (4,61). Various companies are also looking to apply elsewhere the technological knowledge developed in their ESRD activities. Expertise gained in dealing with dialyzer membranes and dialysis systems may prove useful elsewhere. Gambro and other companies, for example, are doing research on plasmapheresis, a process in which blood is separated into its cellular and plasma components by a process of filtration. The technique has potential applications in treating disorders of the autoimmune system, such as myasthenia gravis and hypocholesterolemia (61).

Also related is work on hemoperfusion, which involves the circulation of blood outside the body through an activated charcoal cartridge. By a process of adsorption, various toxic substances, such as those associated with a drug overdose, can be removed (61). While most of the dialyzer companies have already diversified throughout the health care field, the potential for developments and applications in other areas is significant.

6.
Policy Issues

6. Policy Issues

Developments in the industry have been greatly influenced by a number of Federal policy decisions. Most notably, the decision to extend Medicare coverage to end-stage renal disease (ESRD) patients regardless of age set off a dramatic chain of events. The population of beneficiaries grew from roughly 11,000 at the onset of the program to 77,000 today. The industry supplying these patients with equipment and disposables grew with this population.

At present, policy debates continue on a number of issues of critical importance to the market as well as to the patients. The following three sections consider the three major policy areas: reimbursement, research, and dialyzer reuse.

REIMBURSEMENT POLICY

In May of 1983 the Department of Health and Human Services issued final rules for new reimbursement rates for the ESRD program (93). These new rules have caused a great deal of controversy and are expected to have important effects on the industry. This section considers these new rules, discussing their historical antecedents, their form and rationale, and their possible effects.

History of Reimbursement

As dialysis techniques for treating chronic kidney failure were developed in the 1960s, effective treatment of the life-threatening disease became a possibility. Unfortunately, resources were scarce and treatment choices, often involving life or death decisions, had to be made. In response to this dilemma, the U.S. Bureau of the Budget in 1967 created a Committee on Chronic Renal Disease. The committee, known as the Gottschalk Committee, was charged with developing recommendations to deal with these problems. It issued a recommendation that (94):

> . . . a national program be initiated for the treatment of end-stage renal disease with the aim of providing, at the earliest possible date, treatment in the form of chronic dialysis and/or transplantation for all the American population for whom it is medically indicated.

The committee suggested that the program be financed by amending the Social Security Act "to cover the permanently disabled regardless of age" (94).

From the late 1960s until 1972, over 100 bills were submitted in Congress to deal with the ESRD problem (73). However, it was not until 1972 that the issue was fully addressed. Section 1991 of the Social Security Amendments of 1972 extended Medicare health insurance coverage to those people under age 65 suffering from chronic renal disease and requiring dialysis or transplantation. The effective date for the coverage was July 1, 1973 (108). As of 1982, the program covered about 93 percent of the ESRD patient population (20).

In establishing the actual reimbursement levels for dialysis under Medicare, the Social Security Administration's Bureau of Health Insurance had little to go on. The non-Medicare medical market varied widely in reimbursement practices (72). The decision was made to pay 80 percent of the average cost to a hospital-based facility or 80 percent of the reasonable charges for a free-standing facility, up to a "screen" or limit, of $133 per treatment. If routine laboratory services were included in the facility's costs, the screen was raised by $5; if the supervisory services of a physician were included in the facility's costs, the screen was increased by $12 more to $150. These rates were in effect from 1974 until just recently when they were supplanted by the new rates discussed below (108).

In 1982, prior to the new rules, nearly all free-standing facilities were being paid at the rate of $138 per treatment (the $133 plus $5 laboratory charge) (20). Most hospital-based facilities re-

quested and were granted exceptions to the screen, on the grounds that their costs were higher; and the average payment to hospitals had risen by 1980 to approximately $159 per treatment (110).

Under the previous system, physicians could choose from one of two systems of payment, the initial method and the alternative reimbursement method. Under the initial method, reimbursement for supervisory care was paid to a facility as part of its reimbursement rate, as mentioned above. The physician was then paid by the facility for these supervisory services. Other nonsupervisory services were paid on a fee-for-service basis. Under the alternative reimbursement method, physicians were paid a comprehensive monthly fee per patient. For patients dialyzed in facilities, the fee was based on a calculation of the customary or prevailing charges for a followup visit, multiplied by 20. In 1982 the fee averaged roughly $220 per month. For supervisory home patients, the weighting factor was 14 rather than 20, to reflect the presumed lower physician service requirements of patients on home dialysis. This fee came to an average of $154 per patient per month in 1982 (20,110).

These payments to physicians and facilities reflect payments under the patients' Medicare coverage. Patients have been enrolled under Parts A and B of the Medicare program. Part A (Hospital Insurance) covers, with some benefit limits, the reasonable and necessary services received in a participating facility. These would include inpatient dialysis. ESRD patients generally receive dialysis on an outpatient basis. This is covered by Part B (Supplemental Medical Insurance). ESRD beneficiaries pay a monthly premium and are entitled to payment of 80 percent of reasonable charges or costs above a deductible. Physicians' fees are paid on the same basis. Patients are responsible for the remaining 20 percent of charges. However, most patients are privately coinsured for this 20 percent, and hospital facilities often waive the 20 percent for those who are not (64).

Home dialysis has been covered under this same basic arrangement. Medicare pays 80 percent of acceptable costs for supplies and equipment and physicians' services, above the deductible. Some inequities in defining supplies were corrected early in the program so as not to penalize home dialysis patients (72). Then, in 1978, passage of Public Law 95-292 offered another incentive. If the patient obtained home dialysis and equipment from an approved facility that reserved the equipment for the exclusive use of patients on home dialysis, the reimbursement rate would be 100 percent. At the same time the law set a target rate for home dialysis reimbursement to facilities of no more than 70 percent of the national average payment for in-facility dialysis. The target rate did not apply to CAPD but notably did include payment for home dialysis aides. (The 70 percent limit was raised to 75 percent by the Omnibus Budget Reconciliation Act of 1981 (108)).

Kidney transplantation is paid for by both parts of Medicare. Hospital insurance (Part A) covers various inpatient hospital services associated with the transplant. This includes the cost of obtaining a suitable kidney. Coverage also extends to the care of a patient who donates a kidney. The surgeon's services are covered by Part B. After the deductible is met, Medicare medical insurance pays 80 percent of the recognized charges for a surgeon's services (108).

The New Reimbursement Rates

The costs of the ESRD program have increased dramatically. From $229 million in 1974, expenditures rose to about $1.8 billion in 1982 ($1.2 billion in constant 1974 dollars) (20). This continued growth has generated considerable concern, even though, as Rettig has pointed out, the increase was due more to an increased patient population, which more than tripled over this period, than to an increase in costs per patient (72).

A major impetus for change was the passage of the End Stage Renal Disease Amendment of 1978 (Public Law 95-292). As noted above, a major purpose of the law was to increase incentives for home dialysis. In addition, section 1881 of the law directed that a system be established for "prospectively set" reimbursement rates. Implementation of this provision proved rather time-consuming. In 1979 draft regulations were developed proposing a single rate for outpatient dialysis covering both hospital and free-standing facilities.

However, in 1980 the Health Care Financing Administration (HCFA) proposed a dual rate system, one for hospitals and a different one for free-standing facilities. This proposal was a recognition of the difference in payment rates that had developed from Medicare's practice of granting to hospital facilities of numerous exceptions to the payment screen (73). Although the Reagan Administration indicated in 1981 some preference for a single rate, a final compromise, the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) indicated preference for a dual composite rate: one rate for hospitals and one for free-standing facilities, but each would apply whether patients were dialyzed in the institutional setting or at home (73,108).

By early 1981, the Department of Health and Human Services had developed specific proposed rates. The reimbursement rate was to average $132 for hospital-based facilities and $128 for free-standing facilities. Rates would be allowed to vary to reflect local labor costs. As a result, payments could vary from a low of $114 to a high of $148 for hospitals and from $109 to $143 for free-standing facilities (20,93).

The method by which these figures were generated is illuminating. In response to the 1978 legislation HCFA conducted audits of 38 free-standing facilities and 67 hospitals. *Median* cost per in-facility dialysis treatment was estimated at $108 for free-standing facilities and $135 for hospital-based facilities. In response to the 1981 legislation calling for composite rates, audits were then conducted on 25 large home dialysis programs. From this audit a median cost of $97 per treatment was estimated. These costs were then weighted by the percentage of patients estimated to be dialyzing in-facility and at home. The hospital rate was then raised by $2.10 "to account for an apparent excess in hospital overhead costs resulting from Medicare hospital accounting requirements." Then 5 percent more was added to hospital costs to account for "the possibility that the methodology used may have failed to recognize fully the legitimate costs of hospitals or shortcomings in the audited data" (20).

For physicians the proposed changes eliminated the initial method of payment and modified the alternative reimbursement method. The payment would be the same for in-facility and home patients and was calculated as a weighted average. For patients, one direct change was to eliminate the 100 percent reimbursement option for home dialysis equipment. However, as is suggested below, indirect effects could be more substantial.

In congressional hearings in 1982, critics pointed out various perceived problems with the proposals (110). Opponents criticized the quality of the audits, the sample size, the underlying assumptions, the philosophical rationale, and much else. Overall, HCFA received 507 petitions and 4,265 comments on the rules, 3,675 of these from patients (93). The statistical procedures underlying the calculations did seem suspect. Partly in response to that, HCFA pledged additional audits. Nevertheless, the final rules, which were published in the Federal Register on May 11, 1983, and which became effective August 1, 1983, showed very little change from the proposals. The average reimbursement rates of $131 for hospitals and $127 for free-standing facilities were $1 lower than those stated in the earlier proposal. However, this difference simply reflected updated information on the geographical wage differentials that were used in rate calculations (93).

Effects of the Rates

The legislation mandating new rates spoke of their "prospective" nature. Fixed rates are designed to encourage facilities to control costs. Any excess of the rates over incurred costs can be kept by the facility; any deficit in costs must be absorbed. In addition, the composite nature of the rates is meant to create an incentive for movement toward increased home dialysis. HCFA believes that as many as 40 percent of the ESRD population could be on this presumably less expensive modality. Indeed, Carolyne Davis, the Administrator of HCFA, stated that "the promotion of this incentive is the most important objective of the 1981 legislative provisions and of our regulations" (20).

Thus, the regulations are aimed at providing some overall cost-control incentives and at shifting treatment to the home setting. In neither case

is this motivation entirely new. A screen on Medical payments for dialysis treatment has been in effect for a decade. For free-standing facilities the $138 screen was, in effect, a prospectively set rate. Indeed, if the HCFA audits are accurate, these facilities were enjoying an operating profit of about $30 per treatment. Cost reductions could have been translated into profits for these facilities, precisely as called for in a prospective reimbursement system. For hospitals, of course, the screen could be circumvented by the exceptions process. Nevertheless, although Administrator Davis describes the previous system as cost-based (20), the screen did at least impose some administrative discouragement to increasing costs. Apparently, it has made some contribution toward shifting patients toward the more cost-efficient proprietary facilities. Rettig argues that the screen was "imaginative" and "the primary reason for steady per-patient costs" (72). HCFA's plans to be stricter in granting exceptions (93) should enhance the screen's effects.

The incentive for home dialysis is in some respects ironic. In 1972 home dialysis was the choice of approximately 40 percent of the patients, but the initial Medicare regulations discouraged it, contributing to the relative decline in this treatment choice (72). The 1978 legislation was a clear move toward providing a home incentive. The new regulations also encourage it but in a somewhat different fashion.

A rationale for discussing reimbursement in this report is the expectation that reimbursement rates will, by affecting patient and provider behavior, affect the dialysis equipment and disposables market. This section considers effects by evaluating the likely responses to the rules' objectives of encouraging cost control overall and home dialysis in particular.

Cost Control

A prospective reimbursement system provides an incentive to reduce costs. One way to reduce costs is by lowering the costs of materials and equipment used in the dialysis process. Another is to reduce labor costs. Providers can reduce their costs by pressuring manufacturers to lower the prices they charge. There may be some opportunities here, through strenuous bargaining or forming cooperative buying ventures. GAO suggests that HCFA might negotiate with suppliers (105). If such efforts did lower prices overall, then costs to providers would, of course, decline accordingly.

Manufacturers naturally could suffer from such developments. Profits, especially in areas such as dialyzers, are apparently being squeezed. In fact, those providers paying high prices may be in effect subsidizing other activity. Continued buyer pressure on prices will undoubtedly contribute to the predicted industry shakeout.

Such cost-reduction pressures may be viewed perhaps more positively as providing an incentive for innovative advances. Rettig, for example, cites the development of large surface area dialyzers, which increase the surface area exposed to the blood, reducing required time on dialysis and thus providers' costs, as a technical change that may have been prompted by Federal Government cost-control efforts (72). More generally, a recent study notes that prospective reimbursement systems have provided hospitals with a moderate incentive to adopt cost-saving innovations (75). Such concerns about costs offer a useful signal to manufacturers (53).

Materials costs can also be reduced by increased reuse of dialyzers. The key impetus behind reuse, of course, has always been the effort to control costs. Despite medical claims that reprocessing may actually lead to salutary medical effects, cost considerations are likely to remain the force behind this practice. It appears that as long as current professional opinion remains generally supportive of carefully controlled reuse (e.g., Sadler, 1983 (77)), reimbursement pressures will make the practice increasingly attractive to providers.

Note that this may be especially true since reuse was not explicitly considered in the HCFA cost calculations and no adjustments were made to reflect reuse. The HCFA did note that 25 percent of the independent facilities examined reused dialyzers while only 1 percent of the hospital-based facilities did. It was further suggested that dialyzer reuse does contribute to the cost differences observed (20). If a hospital's costs are

otherwise comparable to the HCFA figures, reuse offers a potential for generating a surplus.

The potential effects of reuse on the dialyzer market were discussed earlier in this report. The pressures generated from reuse could, however, provide a special incentive to manufacturers. Manufacturers insist that today's dialyzers were designed for single use only (117). Yet reuse is a fact. Cost pressures may stimulate design changes that enhance the efficiency or reduce the costs of reprocessing.

Another potential source of cost savings is labor costs. Labor probably constitutes 50 percent or more of the cost of dialysis treatment (91). Thus, reductions in labor costs could generate considerable savings. A potential reduction in labor has been the cause for some concern that care will be shortchanged. The American Association of Nurses and Technicians, for example, expresses a fear that the useful services of social workers, dieticians, and nurses will be reduced (3).

The effects on the dialysis equipment and supplies industry of such actions are not clear-cut, but are probably not detrimental. Labor, equipment, and supplies are to some extent substitutable. As has occurred elsewhere, automation may substitute for certain labor requirements. This, of course, would have positive effects on the producers of the automated equipment. With reuse, there is a complex interaction at work. Reuse does seem to raise a facility's labor costs (e.g., by requiring extra handling of dialyzers) while it reduces material costs. At the same time automated dialysis machines could reduce some of these labor requirements.

Input costs could be reduced by a facility's focusing on "healthier" patients. "Sicker" patients, with special medical problems, require more labor, more care in general. The possibility that hospitals' higher costs are due to their "sicker" patients case mix has been debated. Only limited data are available and they are subject to alternative interpretations. However, a recent study by Plough, et al., does suggest that the case mix in hospital-based facilities includes more severe cases than those in free-standing facilities (69) (see also, (53), (109), and (110)).

Incentives for Home Dialysis

As noted above, a major objective of the new reimbursement plan is to encourage home dialysis. Under the previous system, the expenses for home dialysis were reimbursed according to the actual costs incurred. This was the case whether patients dealt with suppliers directly or through a facility. For facilities, the composite rate now provides some incentive for encouraging this modality. Cost data generally suggest that home dialysis is, on the average, less costly per treatment than dialysis in facilities. Recalling the figures presented earlier in the case study, home hemodialysis is clearly less costly in terms of direct outlays because of the time required for unpaid aides. Similarly, CAPD, a popular home modality, appears less expensive if the costs of patient hospitalization are not included. Since hospitalization costs of this sort are funded under Part A of Medicare, they pose no rate-based disincentive to home dialysis. Thus, on balance, if patients affiliated with a facility are moved to home hemodialysis or CAPD, the hospital has an opportunity to receive a surplus.

The objective of the changes proposed in physician reimbursement was essentially to eliminate the disincentive to home dialysis in the preexisting system, where physicians were reimbursed less under the alternative reimbursement method for home patients than for in-facility patients. This payment differential was based on the view that home patients required less of the physicians' time. Under the compositive alternative reimbursement method, physicians' fees are independent of location, and there is no longer any direct financial reward for setting treatment in the facility.

For patients the situation becomes rather complex. Under the new rules patients may still choose to buy their own supplies and be reimbursed under the prior procedures. However, the new plan eliminates the option to receive 100 percent reimbursement for purchase of a home dialysis machine. Furthermore if home patients now purchasing on their own do choose to operate through the facility, they would risk being responsible for 20 percent of a fixed amount that is higher then 20 percent of the home dialysis costs they are now

incurring. Yet HCFA has suggested that one objective is to direct home patients into affiliating with and receiving all equipment and supplies from a facility (20,87). If there is indeed a profit margin for facilities from home patients, facilities would have an incentive to encourage patients to buy through them. Moreover, greater volume purchases may enable the facility to bargain for lower prices from suppliers. One industry source suggests that, as a result, the percent of patients dealing directly with suppliers on an assignment of benefits basis should fall from approximately 70 percent today (105) to less than 10 percent within 1 year (91).

Under the new plan, the patient has no extra financial incentive and perhaps even weaker incentive than previously for home dialysis. The potential profit incentive built into the composite prospective rate is not for patients. This is quite different from, say, a voucher type system, in which the patients, rather than the facilities, are allocated a fixed dollar amount and then given the option of choosing a treatment from among competing alternatives.

Overall, the strongest incentive for home dialysis belongs to the facilities. This is important, of course, and should create some movement toward increased home dialysis. What effects would this have on the industry? If the movement were simply from in-center hemodialysis to home hemodialysis, the effects would probably be to increase sales. Equipment and disposable requirements would be technically similar. However, patients at home would not be able to share machines as would be the case in facilities. Without this opportunity to economize on machines, more machines would be demanded for any given patient population.

However, most new home patients are choosing CAPD (14). This has led many analysts to predict significant growth in this market. Firms such as Baxter Travenol that have a firm foothold in the market may gain at the expense of others that do not. At the same time, many firms focusing on hemodialysis will be encouraged to diversify into CAPD products (47,79). Depending on the relative success of the firms, changes in industry structure are certainly possible. Much, of course, will also depend on how present uncertainties about CAPD's cost and clinical efficacy are resolved.

RESEARCH POLICY

The research activities of the Federal Government have played an important part in the development of knowledge on the causes and treatment of ESRD. The National Institutes of Health (NIH) funded early work on maintenance dialysis and supported research on transplantation as well. The Veterans Administration (VA) and the Public Health Service provided resources for the demonstration of maintenance dialysis therapy. The research support continues today, but some difficult policy issues are evident.

The primary source of research on kidney disease-related research is NIH. Within NIH, the institute doing most of this research is the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), formerly the National Institute of Arthritis, Metabolism, and Digestive Diseases. Other institutes also support kidney-related research as it relates to their special responsibilities. These include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institutes of Dental Research, the National Institute of Child Health and Human Development, and the Division of Research Resources. Overall, the total amount spent on kidney-related research was estimated at about $90 million in 1982 (78). This might be compared with the approximately $73 million spent by NIH on kidney and urinary diseases in 1979 and the $47 million spent in the area in 1976 (101).

This research would be expected to have some long-term effects on the incidence and treatment of ESRD. Perhaps a clearer idea could be obtained by focusing attention on NIADDK, whose over-

all contributions to improving dialysis treatment appear to be significant. According to testimony before Congress by the institute's Acting Director, Lester Salans, in 1982, NIADDK's activities "have produced, directly, or indirectly, most of the innovations and developments which undergird today's maintenance dialysis treatment . . ." (78). The list of these innovations presented in table 14 is impressive. Certainly, these developments have had an effect on the equipment market, particularly the dialyzer market, for NIADDK contributed to the development of the hollow fiber dialyzer.

An examination of trends in funding, however, suggests that NIADDK's direct contributions to the market are likely to decline. Table 15 shows figures for 1979-83 for the Chronic Renal Disease Program, a subdivision within NIADDK's Kidney and Urologic Diseases Program. After an adjustment for inflation, overall spending for the Chronic Renal Disease Program fell by roughly 12 percent. In the area of maintenance therapies, which includes applied research on hemodialysis, peritoneal dialysis, hemofiltration, and other aspects of therapy, research fell by 83 percent from 1979 to 1983. Furthermore, within NIH as a whole, maintenance therapies took up only about 6 percent of the ESRD-related research (119).

Table 14.—Innovations in Dialysis Treatment Attributed to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

- Development of hollow fiber dialyzers.
- Enhancement of efficiency of flat-plate dialyzers.
- Introduction of "single-needle" dialyzers.
- Determination of protein levels for diets for dialysis patients.
- Establishment of national registry of patients on dialysis (responsibility later assumed by HCFA).
- Development of specific adsorbents for uremic wastes.
- Development of wearable artificial kidney for self-treatment.
- Improvement in prevention and treatment of chronic bone pain and bone fractures in patients.
- Development of treatment measures for chronic anemia in patients.
- Development of concept of hemofiltration.

SOURCE: Adapted from L. B. Salans, Acting Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, testimony at hearing, *The End-Stage Renal Diseases Program (Part 2—Treatment Standards and Methods)*, before the Subcommittee on Government Operations, U.S. House of Representatives, Apr. 28, 1982 (Washington, DC: U.S. Government Printing Office, 1982).

This decline in dialysis research appears quite conscious. Congressional testimony puts forward the view within NIH that needs are changing. Particularly noteworthy is the "movement . . . of industry into this [dialysis] field." Given the research base provided by NIH, the view holds, private industry is now ready to take the major responsibility for research in dialysis. Thus, NIH becomes able to focus more heavily on alternatives, such as the underlying causes of the disease and on transplantation. Along with this shift comes an emphasis on investigator-initiated research and a deemphasis on contracts aimed at particular programs (78).

To many observers, such as Blagg, the result is a "deficiency in dialysis research" (12). They can point to various projects with worthwhile objectives that cannot be accomplished because of a lack of funds. They can also point to successes of the sort referred to in table 14 to indicate that past federally funded research in dialysis has been fruitful. For industry, the change in emphasis is important. The NIH research has served as a useful complement to the industry's own research and development (R&D) activities. As the Federal research contribution in this area diminishes, industry will probably find its own research efforts in dialysis becoming more costly.

From an economic perspective, expenditures on dialysis research have to be compared with alternative uses of these funds. A choice must be made as to how much to spend on all research overall, then which specific project should receive funding. Rarely is there adequate quantitative information on benefits and costs on which to make these judgments. In the absence of such information it is appropriate to rely, as NIH has, on the scientific community for judgments on which projects have scientific merit and on Congress and the executive branch for judgments as to which projects have special social merit.

This is a complex but sensible method for deciding research priorities. However, the situation in dialysis is complicated by assumptions underlying the NIH decisions. NIH is suggesting that research on dialysis may indeed be worthwhile but that industry can be expected to step in to see that sufficient research is performed. Is

Table 15.--Research Support for Chronic Renal Disease Program of National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, 1979-83

	Fiscal year											
	1979		1980		1981		1982		1983		Percent change 1979-83	
	Current $	Percent	Current $	Percent	Current $	Percent	Current $	Percent	Current $	Percent	Current $	Constant $[a]
Pathophysiology ..	$2,986,058	32%	$2,745,229	35%	$3,050,031	37%	$3,698,842	42%	$6,221,596	53%	+108	+46
Transplantation ...	1,933,590	21	2,652,601	34	3,488,265	42	3,915,709	44	4,428,662	38	+129	+61
Maintenance therapies	4,435,899	47	2,412,880	31	1,779,284	21	1,192,758	14	1,043,157	9	- 77	-83
Total.....	$9,355,547	100%	$7,810,710	100%	$8,317,580	100%	$8,807,309	100%	$11,693,415	100%	+ 25	-12

[a]Conversion to constant prices was accomplished by using implicit GNP deflator (a price index) for Federal Government purchases of goods and services (U.S. Department of Commerce, Bureau of Economic Analysis, *Survey of Current Business*, March 1984).

SOURCE: L. B. Salans, Acting Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, testimony at hearing, *The End-Stage Renal Diseases Program (Part 2—Treatment Standards and Methods)*, before the Subcommittee on Government Operations, House of Representatives, Apr. 28, 1982 (Washington, DC: U.S. Government Printing Office, 1982); and G. H. Hirschman, Chronic Renal Disease Program, National Institutes of Health, Bethesda, MD, personal communication, March 1984.

this a reasonable expectation? In some respects it is. If, as NIH asserts, a strong technological base has already been provided, then industry may be expected to perform the development work required for commercializing worthwhile new technologies. Nevertheless, a diminishing NIH research base is apt to be viewed by firms as offering diminishing attractive commercial opportunities. A further difficulty is that an industrial firm will make judgments on R&D based on the expected return to the firm rather than on the overall value of the innovation to society. As various authors have suggested (e.g., (6) and (56)), there are numerous projects where the returns to society may be high but where the returns to the private firm may be so low as to make the project unattractive. This results because an innovator is generally unable to appropriate fully the gains of an innovation. As the market reacts to these innovations, competitors and even customers manage to secure for themselves part of these gains.

The end result is that private firms may, from a social perspective, underspend on R&D and may choose a socially suboptimal mix of R&D projects. Policies to correct this problem need not, in general, include direct Government grants for R&D, but they may involve various other incentives such as tax breaks. However, for some studies, particularly those of an evaluative nature, potential conflicts of interest may call for direct Government involvement. For example, clinical trials of hemodialyzer reuse or of CAPD may be more valuable and widely accepted if funded by impartial sources. And further, such purely evaluative studies are apt to be especially characteristic of projects where the benefits to society are well beyond what the firm is likely to gain for itself.

A related difficulty here is the potential for differences of opinion among Government agencies with respect to who should fund particular research. An example is the controversy, discussed in congressional hearings in 1982 (107) as to which agency, HCFA or NIH, should fund research on reuse of hemodialyzers. NIADDK had funded a study, completed in June 1981, on multiple use (see (22)). However, in the testimony, the Institute's view is expressed that, because the issue had now emerged as primarily one of economic impact, HCFA would be best suited to fund additional clinical trials; HCFA, on the other hand, viewed its research role as purely economic and "appropriate only after clinical issues have been resolved" (119).

An intradepartmental ESRD workgroup set up to help resolve such differences subsequently recommended that the Food and Drug Administration be given the responsibility for the clinical trials (20,40). Meanwhile, many questions about reuse remain unanswered. This example suggests that an appropriate Government research program in ESRD should clearly delineate not only research objectives but also research responsibilities.

DIALYZER REUSE AND THE FEDERAL GOVERNMENT

Federal Government policies have had an important influence on the practice of reuse of dialyzers. These policies include the reimbursement policies discussed earlier, which provide incentives for cost control and, thus, cost-saving techniques such as reuse. However, other policies have had a more direct influence. These include funding of research on reuse and actions related to the regulation of medical devices.

Various research efforts that deal with reuse have been supported by Federal funds. For example, the Artificial Kidney-Chronic Uremia Program within NIH sponsored work on the reuse of coil dialyzers (e.g., see (85)). This study concluded that reuse of coils did indeed appear safe and cost effective. The National Institute of Arthritis, Metabolism, and Digestive Diseases also partially supported research on reuse by Dr. Karl

Nolph and his associates (9,65,118). This work evaluated reuse of coil and hollow fiber dialyzers under various conditions.

In 1978 Congress passed an amendment to the Social Security Law (Public Law 95-292) requiring the Secretary of Health and Human Services to conduct a "study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients." Subsequently, NIADDK did sponsor a study evaluating dialyzer reprocessing (see (22)). The Centers for Disease Control also did work that indicated that reuse was not associated with the increased incidence of hepatitis B infections among dialysis patients and staff (see (28)). Thus, the Federal Government has contributed to the development of knowledge on reuse. The Federal Government's interest in reuse remains high. However, as noted in the previous section, there are differences of opinion as to which Federal agencies will support or conduct the research.

A key role in the history and future of reuse belongs to the Food and Drug Administration (FDA). This role is associated with the FDA's regulatory functions under the 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act. These amendments give FDA authority to regulate medical devices in order to assure that they are safe and effective. The regulations apply to all medical devices and in general appear to pose no special or unusual problems for dialysis equipment. Reuse is affected because regulatory authority extends to dialyzers and to equipment utilized in dialyzer reprocessing.

As noted earlier, most dialyzers are labeled by the manufacturer as being for single use. Under the regulations, any relabeling would require the manufacturer to seek FDA approval. Given the extensive clinical experience with reuse, the FDA may eventually determine that specific dialyzers, when reprocessed according to rigorous reprocessing procedures provided in the manufacturer's labeling, are as safe and effective as dialyzers not previously used (113). Although FDA's response cannot be assured and seeking FDA approval would involve some administrative expenses, manufacturers' reasons for not seeking to relabel stem largely from considerations other than FDA. One may simply be their belief that reuse is medically inappropriate. Another reason may be concern about the market's reaction: Relabeling may stimulate even further the practice of reuse and contribute to declining demand for new dialyzers. Finally, manufacturers may have concerns about product liability. Labeling a dialyzer as suitable for reuse could make manufacturers liable for any damages to a patient from reuse. However, although the legal situation is potentially complex, manufacturers do have reason to know that dialyzers are reused and, thus, may be liable regardless of labeling (36).

Of course, regardless of the labeling, reuse has become a common practice. The FDA is obviously aware of this. Its position regarding reuse of dialyzers (and other disposables) was stated in a policy guide for field staff issued in 1977 and revised in 1981 (99,100). The FDA indicates that "the user should be able to demonstrate that a device considered for reprocessing can in fact be adequately cleaned and sterilized without affecting the characteristics and qualities of the device and, moreover, that the device will remain safe and effective for its intended use. In addition the institution or practitioner who reuses the disposable device must bear full responsibility for its subsequent safety and effectiveness" (116).

Although the FDA "neither condemns nor condones dialyzer reuse" (116), it has made some efforts to contribute to the evaluation of the practice. The FDA was one of the sponsors of a National Workshop on Reuse of Consumables in Hemodialysis in 1982. This workshop reached a consensus for the development of guidelines for hemodialyzer reuse.

The FDA has also authorized the marketing of an automated dialyzer reprocessing device. Under the Medical Device Amendments, entirely new devices may be subject to premarket approval by the FDA. However, if a device is "substantially equivalent" to a device marketed prior to the enactment of the amendments, then a manufacturer can submit information required for premarket notification (106). In this latter case the FDA will consider whether the device is similar to and as safe and effective as the preexisting device. The reprocessing device was deemed sub-

stantially equivalent and allowed to be marketed. Such permission does not constitute FDA *approval* of the device (116).

Overall, FDA response to reuse has been cautious. It recognizes that reuse is widespread and, from available evidence, not a hazard to the public health. At the same time it is reluctant to endorse formally a practice which most experts agree should be the subject of further clinical trials. The FDA has chosen to monitor the activity and to emphasize the responsibility of providers to ensure safety and effectiveness.

However, the literature on reuse suggests that the practice's safety depends critically on the quality of the reprocessing. This suggests that in the future FDA might want to step in to assure that reprocessing is done appropriately. The manufacturing industry would be expected to be generally supportive, since it has argued, as noted earlier, that clinics and hospitals reusing dialyzers should be subject to good manufacturing practices guidelines. This has not yet been done, but California has recently passed legislation requiring the establishment of appropriate reprocessing methods (44). Furthermore, if independent reprocessing service companies do become important, they may be viewed as falling under GMP guidelines. As suggested earlier, however, this need not pose a serious threat to the economic viability of such reprocessing activities.

Appendixes

Appendix A.—Capsule Descriptions of Major Firms in the Industry

Abbott Laboratories

Abbott Labs is a large producer of various healthcare products, including pharmaceuticals and nutritional products as well as laboratory and hospital instruments. Total company sales were about $3 billion in 1983. As of 1980 its sales of dialysis products were extremely small, but the company is moving into the CAPD market (5,79).

Asahi Medical Co.

This Japanese company is a subsidiary of the $3.5 billion Asahi Chemical Co. It has been in the dialysis equipment market since about 1975 and began full-scale marketing of its hollow fiber dialyzer in 1979. Although still relatively unknown in the United States, the company is a major force in Japan and the world. Some observers expect a movement by Asahi into the U.S. dialyzer market. The company's licensing arrangement with Cordis Dow apparently prevented U.S. sales until 1983 (7,8,57,79).

Baxter Travenol Laboratories

This company is involved in producing a wide range of medical care products. Its renal and urological therapy product line represents about 20 percent of its total sales of $1.7 billion (10). It is active in producing both disposables and equipment for hemodialysis. The company has also made a strong effort in the CAPD market, where it has captured a 90-percent share (5).

BD Drake Willock

As of 1976, this company has been part of Becton Dickinson, which now has over $1 billion in sales of various medical, laboratory, and industrial equipment. The company has focused its efforts on equipment rather than disposables. However, Becton Dickinson has expressed an interest in selling Drake Willock (11).

CD Medical, Inc.

CD Medical is the successor to Cordis Dow. The company was created in 1983 when the Dow Chemical Corp. purchased Cordis Corp.'s 50 percent interest in their joint venture, Cordis Dow, for $4 million in cash and real estate (114). The company has been engaged primarily in the production of hollow fiber dialyzers, and, indeed, the joint venture was established in part as a mechanism to utilize Dow's patents on hollow fiber technology. The company has experienced some difficulties, including some losses, in recent years (17,59,114,115).

Cobe Laboratories

Cobe entered the hemodialysis market in the late 1960s. The company offers a complete line of equipment and supplies, and, indeed, has emphasized a complete system approach in its marketing activities. It is focused in this market, with about three-quarters of its approximately $100 million in sales coming from hemodialysis products (5,60).

Erika

Erika is a subsidiary of National Medical Care, the largest provider of outpatient dialysis care through its approximately 180 centers treating more than 13,000 patients (88). Erika produces and distributes a variety of dialysis products to both its parent and unaffiliated customers. Sales of artificial kidney products accounted for about 13 percent of National Medical Care's $295.5 million in sales in 1982 (5,63).

Extracorporeal

Extracorporeal produces both disposables and equipment for hemodialysis. It is also integrated backwards into the manufacture of membranes for dialyzers. Since 1978 it has been a subsidiary of Johnson & Johnson, a large medical care products company with almost $6 billion in sales in 1983. As of 1980, Extracorporeal represented only about 2 percent of the parent company's sales (5,45,68,79).

Gambro AB

Gambro is an international company incorporated in Sweden. Shares of the company are publicly traded, but close to 80 percent of the voting stock is controlled by members of the family of Holger Crafoord, a Swedish industrialist who founded the company in 1965. Gambro is the world's largest producer of hemodialysis and hemofiltration products, but its sales are widely dispersed, with no more than 20 percent coming from any one country. It has had manufacturing facilities in the United States for several years (61,68).

Hospal

Hospal manufactures dialyzers as a joint venture of Rhone-Poulenc and Sandoz Ltd. Rhone-Poulenc is a multibillion-dollar French company, nationalized since 1982, that makes various chemical, pharmaceutical, and textile products. Sandoz Ltd. is Swiss and also has sales in the billions of dollars. Its activities range from chemicals and pharmaceuticals to seed and food products. Its pharmaceutical products include cyclosporine, which is used for transplant purposes (58,74).

Organon Teknika Corp.

This manufacturer of dialysis and other medical products falls within a complex organizational structure. The company is 50 percent owned by Organon Teknika N.V., a subsidiary of Akzo N.V., a Dutch holding company, and Akzona, Inc., of the United States. Within the Akzo empire is also Enka, a major manufacturer of membranes for dialyzers (2,57).

Terumo Corp.

Terumo is a Japanese-based multinational corporation involved in the manufacture and sale of a variety of medical products. Consolidated net sales of the company were 62 billion yen (approximately $265 million) in 1981. U.S. operations include a sales office in California and a production facility in Maryland (90). The company is Japan's second largest producer (behind Asahi) of hollow fiber dialyzers (39).

Toray Industries, Inc.

This company is engaged in the production of fibers, plastics, and chemicals and has annual sales in excess of $3 billion. It is Japan's third largest hollow fiber dialyzer producer (behind Asahi and Terumo) and is reported by Information Resources International as planning to market in the United States in 1983 (39, 57,92).

Appendix B.—Glossary of Terms and Acronyms

Glossary of Terms

Artificial kidney: See *dialyzer*.

Coil dialyzer: A dialyzer in which the blood passes through semipermeable membrane tubing. The tubing is wound around itself, or "coiled," and a supporting screen separates the coils. The dialysate passes at a 90° angle through the space created by the screen.

Concentration ratio: The share of market output accounted for by the largest firms in an industry—usually by the four largest. Higher values are indicative of greater concentration of economic power and less competitiveness.

Continuous ambulatory peritoneal dialysis (CAPD): A form of peritoneal dialysis in which there is a continuous manual exchange of dialysate from the peritoneal cavity.

Continuous cycling peritoneal dialysis (CCPD): A form of peritoneal dialysis in which a machine cycles the dialysate in and out of the peritoneal cavity automatically about every 4 hours overnight as the patient sleeps.

Dialysate: A fluid that is used in the dialysis process, which contains desirable concentrations of physiological chemicals. During dialysis, the dialysate is separated from the patient's blood by a semipermeable membrane.

Dialyzer: A device used in hemodialysis. It consists of a compartment for the blood, a compartment for the dialysate, and a semipermeable membrane separating the two. The three principal types are coil, hollow fiber, and parallel plate.

End-stage renal disease (ESRD): A condition of irreversible kidney failure. Without treatment, the disease results in the patient's death.

Hemodialysis: A process by which blood is pumped from the patient's body into a dialyzer and then returned to the body in a continuous extracorporeal blood loop. While in the dialyzer the blood flows next to but separate from another fluid, a dialysate. The blood and the dialysate are separated from each other by a semipermeable membrane. Via diffusion and osmosis, waste products and other molecules pass through the semipermeable membrane and the blood can again take on its appropriate properties.

Hemodialyzer: See *dialyzer*.

Herfindahl index: A measure of economic market concentration. It is calculated by summing the squares of the market shares of the firms in the market. Higher values of the index indicate a greater degree of concentration and a less competitive market structure.

Hollow fiber dialyzer: A dialyzer containing thousands of hollow fibers bundled within a compact cylinder. Blood flows through the semipermeable hollow fibers while the dialysate passes outside the fibers.

Intermittent peritoneal dialysis (IPD): A form of peritoneal dialysis involving intermittent treatment three to four times per week. Typically, the patient is dialyzed for about 12 hours on each treatment.

Parallel plate dialyzer: A dialyzer consisting of a stack of semipermeable membranes sandwiched between support plates. Blood passes through the membranes while the dialysate passes in the opposite direction through grooves or spaces in the support plate.

Peritoneal dialysis: A process in which dialysis occurs within the patient's body rather than via an extracorporeal blood loop, as is done in hemodialysis. A permanent catheter is inserted into the abdomen and then dialysate is entered through the catheter into the peritoneal cavity. The fluid is allowed to remain for varying periods of time, during which dialysis occurs across the semipermeable peritoneal membrane. Later, the dialysate is drained out through the catheter and discarded.

Peritonitis: An inflammation of the peritoneum, the smooth transparent serous membrane that lines the cavity of the abdomen.

Prospective reimbursement: The setting of reimbursement rates prospectively, i.e., in advance of the actual provision of care. This is to be contrasted with cost-based or retrospective reimbursement, in which rates reflect actual costs incurred.

Reuse: With respect to dialysis, this occurs when a dialyzer, after its original use, is reprocessed, stored, and then used again on the same patient, often multiple times.

Transplantation: With respect to kidneys, the transplanting of a healthy kidney from a donor, living or recently deceased, into a patient with kidney disease.

Glossary of Acronyms

CAPD	—continuous ambulatory peritoneal dialysis
CCPD	—continuous cycling peritoneal dialysis
ESRD	—end-stage renal disease
FDA	—Food and Drug Administration, Department of Health and Human Services
GAO	—General Accounting Office
GMP	—good manufacturing practices
HCFA	—Health Care Financing Administration, Department of Health and Human Services
IPD	—intermittent peritoneal dialysis

NIADDK—National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services
NIH —National Institutes of Health, Department of Health and Human Services
NMC —National Medical Care, Inc.
OTA —Office of Technology Assessment, U.S. Congress
R&D —research and development
VA —Veterans Administration

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